BEAR® 1000
VENTILATOR

Instruction Manual

P/N 50-10613-00

11/97

User/Owner Responsibility

This Bear Medical Systems, Inc. (hereafter referred to as "Bear") equipment and the authorized accessories for it are designed to function as specified in the relevant instruction manual only when operated, maintained, and repaired in accordance with supplied manuals and instructions. This equipment must be periodically checked, recalibrated, maintained, and components repaired and replaced when necessary for the equipment to operate reliably. Parts that have failed, in whole or in part, exhibit excessive wear, are contaminated, or are otherwise at the end of their useful life should not be used and should be replaced immediately with parts supplied by Bear or parts which are otherwise approved by Bear. Equipment which is not functioning correctly or is otherwise in need of repair or maintenance must not be used until all necessary repairs and/or maintenance have been completed and a factory authorized service representative has determined that the equipment is fit and ready for use. This equipment and any of its accessories or component parts should not be modified.

The owner/user of this equipment shall have sole responsibility and liability for any damage or injury to persons or property (including the equipment itself) resulting from operation not in accordance with the authorized maintenance instructions, from repair by anyone other than a factory authorized representative, modification of the equipment or accessories, or from the use of components or accessories that have either been damaged or not authorized for use with this equipment by the factory.

Warranty

The Bear Medical Systems, Inc. standard warranty is extended to the original buyer purchasing the equipment directly from Bear or through its authorized dealers. All warranty periods, where applicable, commence on the date of first purchase, but not more than six months after shipment from Bear.

Bear's sole obligation and liability under this warranty is limited to (at Bear's option) the repair or replacement by Bear's authorized personnel of any parts or assemblies which, upon test and examination by Bear, prove to be defective. This equipment may be returned prepaid to Bear after prior notification has been given and approval obtained for the return.

The warranty does not cover normal maintenance such as cleaning, adjustment or lubrication and updating of equipment or parts thereof. This warranty shall be void and not apply if the equipment, including any of its parts, is modified without Bear's authorization; is attempted to be repaired by personnel not authorized by Bear; is not maintained in accordance with the prescribed schedule; is used with accessories or parts not authorized by Bear; or is damaged due to misuse, mishandling, abuse, negligence, accident, fire or inadequate packaging by owner for shipment. Bear makes no guarantee of clinical results.

THE WARRANTY STATED ABOVE (INCLUDING ITS LIMITATIONS) IS THE ONLY WARRANTY MADE BY BEAR MEDICAL SYSTEMS, INC., AND IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER WRITTEN OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ALLIED SHALL NOT BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND.

TABLE OF CONTENTS

1. INTRODUCTION

OVERVIEW

The BEAR® 1000 Ventilator is available in three models, a Basic, Intermediate and a Comprehensive BEAR® 1000 Ventilator. This instruction manual is intended for use with all models. Please refer to your specific model for the information which is applicable to your BEAR® 1000 Ventilator.

The Base Platform offers:

- Assist CMV
- SIMV (with or without Pressure Support)
- CPAP (with or without Pressure Support)

Additional models offer:

- Pressure Control Ventilation
- PC - SIMV
- Minimum Minute Volume
- Pressure Augmentation
- Lower Tidal Volume
- SMARTTRIGGER® (Base Flow/Flow Trigger)
- For panel details and specifications, please refer to Section 5

Any BEAR®1000 Ventilator model can be upgraded.

PRODUCT SUPPORT

Bear Medical Systems, Inc. is committed to product support, and the Bear regional sales representative is a valuable resource for clinical as well as logistical questions. For additional support, contact Bear Medical Systems, Inc. at the following phone number:

1-800-232-7633
(909)-788-2460

For Information regarding:	Ask the operator for:
Ordering, deliveries or pricing	Customer Service
Clinical Application Questions	Marketing
Service Questions	Technical or Field Service
Biomedical Training	Training Department

WARRANTY

The warranty for your BEAR® 1000 Ventilator is outlined on a card attached to the unit at the time of sale. Please fill out this warranty card and return it. Doing so will ensure that you, as the end user, will receive the full benefit of the warranty period.

The user and owner are responsible to maintain the BEAR® 1000 Ventilator in accordance with the instruction manual. Refer to *Cleaning & Maintenance* (Section 7) in this manual as well as the Maintenance Manual for more details.

WARNINGS & CAUTIONS

It is essential that users become familiar with this entire manual and that they pay careful attention to all Warnings and Cautions before using the BEAR® 1000 Ventilator on any patient.

WARNING Means there is a possibility of personal injury or death to the patient or others.

Means there is a possibility of damage to the equipment or other property.

In general, Warnings and Cautions have been located within the manual wherever they are most meaningful.

However, certain Warnings and Cautions are general to the use of the ventilator under all circumstances. Accordingly, these advisories are included in this *Introduction section.*

WARNING

The BEAR® 1000 Ventilator is intended for use by a qualified practitioner under the direction of a qualified physician.

When the ventilator is connected to a patient, it is recommended that a health care professional be in attendance at all times to react to an alarm or other indication of a problem.

An audible alarm indicates an anomalous condition and should never go unheeded.

Under no circumstances should the BEAR® 1000 Ventilator be used in the presence of flammable anesthetics due to possible explosion hazard.

Electric shock hazard—Do not remove any of the ventilator covers or panels. Refer all servicing to an authorized service technician.

Antistatic or electrically conductive hoses or tubing should not be used due to electrical shock hazard.

- Warnings continued next page -

WARNING

Always have an alternate means of ventilation available whenever the ventilator is in use.

This equipment has been tested to the European EMC directive; however, the functioning of this equipment may be adversely affected by the operation of other equipment nearby, such as high frequency surgical (diathermy) equipment, defribrillators, short-wave therapy equipment, walkie talkies, or cellular phones.

It is suggested that oxygen concentration be monitored continuously using an oxygen monitor that includes both high and low alarms. If a high or low oxygen percent alarm is activated, an Operational Verification Procedure (OVP) should be performed on both the ventilator and the external oxygen monitor. If the ventilator fails the OVP, it should be referred to an authorized service technician.

Remember that the minimum minute volume must be set to a value greater than the clinician-set (RATE) x (TIDAL VOLUME). If it is set to a lower value, MMV operation will not be effective.

Ensure that the voltage selection on the rear of the BEAR® 1000 Ventilator is set to match the voltage of the wall outlet and the correct fuses are installed or damage to the BEAR® 1000 Ventilator may result.

DO NOT dry the flow sensor with high pressure gas. Doing so can damage the sensor.

DO NOT insert cleaning instruments (brushes, pipe cleaners, etc.) into the flow sensor. Doing so can damage the sensor.

The flow sensor is an integral part of the Flow Trigger system. If a Run Diagnostics alarm is active with an E-34 or E-35 error code (Flow Sensor Fault), Flow Triggering should be discontinued. If an E-34 or E-35 condition is active, possible Flow Trigger de-sensitivity to patient effort will occur.

2. ASSEMBLY

OVERVIEW

The BEAR® 1000 Ventilator is shipped almost fully assembled. A few unpacking and assembly steps remain, as described below.

UNPACKING

Unpack the Ventilator according to the Instructions on the crate.

The BEAR® 1000 Ventilator comes with a Basic Accessory Kit (P/N 50-08600-00) which includes the following:

1. DISS Air Hose, 12 feet.....P/N 50000-01000
2. DISS O_2 Hose, 12 feet.....P/N 50000-01001
3. Flexible Circuit Support Arm .....P/N 52000-30100
4. Circuit Tube Hanger Clip (available in multipacks of 6).....P/N 50000-03099
5. Rail Clamp Bracket for Support Arm .....P/N 52000-30101
6. Proximal Line Bacteria Filter.....P/N 50000-01106
7. Mainflow Bacteria Filter with Coupler....P/N 50000-01054
8. 3/4" Tubing, 14 inches .....P/N 52000-00328
9. Condensate trap (available in multipacks of 3).....P/N 50000-09901
10. Flow Sensor .....P/N 50000-09900
11. Instruction Manual.....P/N 50-10613-00

VISUAL INSPECTION

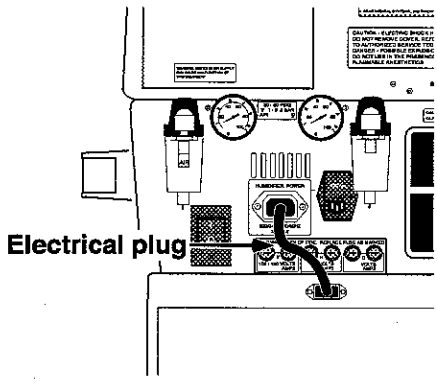
Inspect the exterior for any damage which may have occurred during shipment. In the event that you should find damage, immediately contact the responsible shipping carrier to make a claim. Bear Medical Systems, Inc. will support you with any information needed.

WARRANTY CARD

Find the warranty card attached to the ventilator. Fill out the card and return it to ensure full benefit of the warranty period.

HUMIDIFIER POWER

Verify that the electrical plug from the rear of the cart is plugged into the rear of the ventilator at the receptacle labeled "Humidifier Power," as shown.



CAUTION

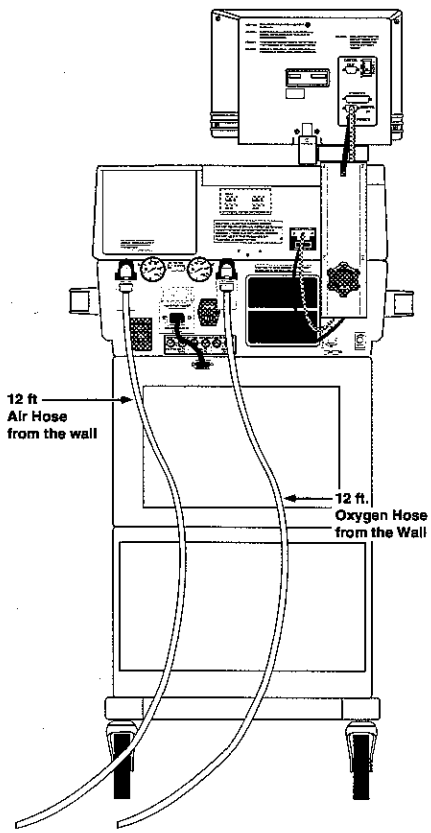
The electrical outlets on the front of the ventilator cart are rated at 500 watts maximum. The front outlet is intended for a humidification device such as a BEAR® VH 820 or an LS 420/460. Malfunction may result if any humidifier with a power rating of greater than 500 watts is plugged into this outlet.

AIR & OXYGEN HOSES

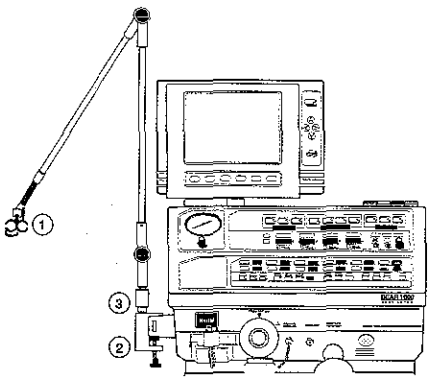
Air and oxygen hoses are provided in the basic accessory kit. Attach the 12-foot DISS oxygen hose to the oxygen inlet fitting located on the rear of the ventilator.

Connect the 12-foot DISS air hose directly to the air inlet fitting located on the rear of the ventilator.

Secure these hoses around the hose storage wraps (located on the rear of the cart) for convenience in transporting the ventilator.



PATIENT CIRCUIT SUPPORT ARM



The patient circuit support arm is installed as shown below.

1) Attach the tube hanger by loosening the arm clip, inserting the tube hanger and retightening the clip.

2) Place the mounting bracket for the support arm onto either of the side rails on the ventilator, and tighten the bracket by turning the knob.

3) Insert the support arm into the bracket, and secure it in place by turning the knurled base of the arm.

This arm has two adjustable joints, allowing the clinician to adjust the bend and orientation of the arm.

DIAGNOSTICS MODE ADJUSTMENTS

Certain one-time setup procedures require that the ventilator be turned on in the Operator Diagnostics mode. There are two such setup procedures, to establish the following:

- An appropriate barometric pressure/altitude setting, and
- A baud rate setting for RS-232 communication with the BEAR® Graphics Display, a bedside monitor, or a computer.

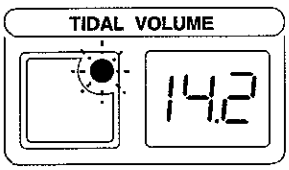
Without attaching a patient circuit, enter the Operator Diagnostics mode as described below:

1) Locate the TEST key on the front panel at the right side of the red Alarm Group.

2) Press and hold this key while reaching to the right rear corner of the ventilator and turning on the power switch. Continue to hold the TEST key until the diagnostics displays appear.

3) Verify that the Operator Diagnostics mode has been activated by observing that the RUN DIAGNOSTICS LED illuminates.

To adjust the barometric pressure (or altitude) setting to accurately reflect the ambient barometric conditions, perform the following steps:



1) Press and release the TIDAL VOLUME key in the green Control Group on the front panel.

2) Notice that the LED on this key now flashes.

3) While this LED flashes, turn the green SET knob located on the right side of the Control Group.

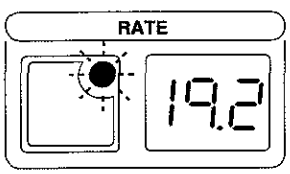
4) Observe the numerical LED adjacent to the TIDAL VOLUME key change within the range from 10.5 to 14.7 psia. Adjust the setting to the absolute barometric pressure which reflects your own circumstances.

The following table will enable you to translate any convenient measure of altitude or barometric pressure into the psia measure required by this setting.

Convert Altitude to Barometric Pressure

Altitude in Feet	Corresponding Barometric Pressure	
	mmHg	psia
0	760	14.7
1000	733	14.2
2000	707	13.7
3000	681	13.2
4000	656	12.7
5000	632	12.2
6000	609	11.8
7000	588	11.4
8000	567	11.0
9000	545	10.5

The second setup performed with the Operator Diagnostics mode is the optional baud rate adjustment. The baud rate is used by the RS-232 connector to digitally communicate with the BEAR® Graphics Display or a computer. If neither device is attached to the BEAR® 1000 Ventilator, there is no need to perform the setup procedure.



1) Press and release the RATE key in the green Control Group on the front panel.

2) Notice that the LED on this key now flashes.

3) While this LED flashes, turn the green SET knob located on the right side of the Control Group.

4) Observe the numerical LED adjacent to the RATE key rotate through four setting level options:

   1.2 (for 1200 Baud)
   2.4 (for 2400 Baud)
   9.6 (for 9600 Baud)
   19.2 (for 19200 Baud)

NOTE

The baud rate **MUST** be set to 19200 Baud for use with the BEAR® Graphics Display.

ALARM LOUDNESS ADJUSTMENT

The alarm loudness on your BEAR® 1000 Ventilator is adjustable from 65 to 83 dB(A).

Adjust this level by following these steps:

1. Starting with the ventilator power off, turn on the power, and wait for the power-up diagnostics to be completed.
2. Locate the ALARM LOUDNESS knob on the lower right hand corner of the rear of the ventilator.
3. Initiate an audible alarm by pressing the TEST key located in the red Alarm Group on the front panel. Turn the ALARM LOUDNESS knob until the desired level is reached.

OPTIONAL GRAPHICS DISPLAY

A BEAR® Graphics Display is available as an upgrade option for your BEAR® 1000 Ventilator. For installation instructions, please refer to the Graphics Display instruction Manual.

OPTIONAL COMPUTER CONNECTION

A computer may be attached to the ventilator. In the absence of a BEAR® Graphics Display, the computer should be attached directly to the RS-232 connector located on the rear hood of the ventilator. Subsequently, the appropriate baud rate for communication with the computer should be set on the ventilator as previously described. Of course, any computer which is connected must be able to communicate via the protocol defined at the end of Section 8.

If a BEAR® Graphics Display has been installed on the BEAR® 1000 Ventilator, the computer should be attached to the optional "Digital Out" connector located on the rear of the Graphics Display itself. Subsequently, the appropriate output baud rate should be selected by way of the Graphic Display menus.

OPTIONAL ANALOG CONNECTION

Three analog signals are available on the BEAR® 1000 Ventilator: pressure, flow and remote alarm. Use the 15-pin connector located on the rear hood of the ventilator to tap these voltage signals, and refer to the *Panel Details & Specifications* (Section 5) for information regarding the voltage range and scale for each of these signals.

NOTE

Special cabling is required to interface the remote alarm feature of the BEAR® 1000 Ventilator to the hospital nurse call system. To support system differences in plug styles, two cable configurations are made available for purchase

- P/N 51000-09855 - BEAR® 1000 Ventilator nurse call cable assembly kit (phone plug)
- P/N 51000-09856 - BEAR® 1000 Ventilator nurse call cable assembly kit (RJ 45 modular plug)

3. SETUP & CHECKOUT

OVERVIEW

Setup and checkout tasks performed repetitively, are described here.

SETTING UP THE REAR OF THE VENTILATOR

To set up your BEAR® 1000 Ventilator for use on a patient, perform the following steps:

First, attach the loose ends of the 12-foot air and oxygen hoses to the respective wall (or other gas source) fittings. (Gas must be supplied at 30-80 psig with a minimum flow rate of 80 LPM).

Next, inspect the integral water traps located at the rear of the ventilator. No condensate should be in these traps.

CAUTION

Do not throw pneumatic hoses or power cords over the top of the ventilator. Doing so can damage the membrane key panels and the underlying electronics. Use the cord wraps provided on the rear of the cart.

Condensate in the water traps warns that condensate may be entering the ventilator. If the compressed air and oxygen entering the ventilator are not clean and dry, ventilator malfunction may result. Therefore, check the water traps periodically.

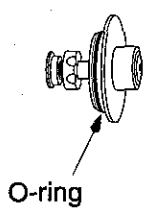
Finally, plug the ventilator power cord into an outlet. A humidifier and the optional Graphics Display should already be connected (see Section 2) and ready to power up.

SETTING UP THE FRONT OF THE VENTILATOR

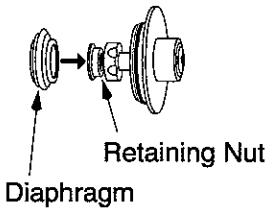
To prepare the front of the ventilator for use on a patient, you will need to:

- attach the exhalation valve,
- install the external flow sensor, and
- attach a patient circuit.

These procedures are described in the following paragraphs.



Inspect the o-ring on the exhalation valve Diaphragm Mounting Base Assembly to be sure it is not worn. Replace it if there is any evidence of cracking or deformation (Part Number 50000-08607).

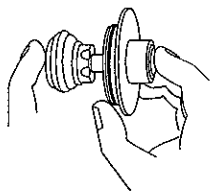


To install the exhalation valve diaphragm, insert the small end of the Diaphragm Mounting Base Assembly into the open end of the diaphragm, as shown.

Pull on the diaphragm to seat it properly.

Turn the retaining nut until it stops over the end of the diaphragm. (The nut is designed with a built-in stop to ensure the diaphragm will not be damaged.)

Check that the diaphragm is properly assembled and free of pinholes.

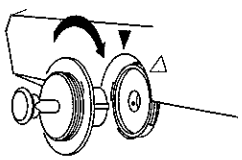


1. Pull out (and thus fill) the diaphragm,
2. Cover the opposite end of the Diaphragm Mounting Base Assembly with a finger, and press on the diaphragm.

The diaphragm should not deflate. If it does, it is installed improperly, or there is a hole in the diaphragm.

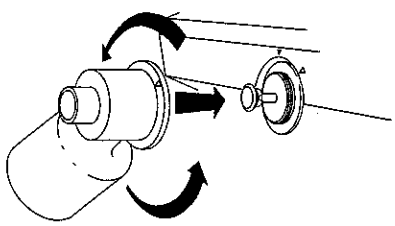
WARNING

Use of a damaged diaphragm may result in improper ventilation.



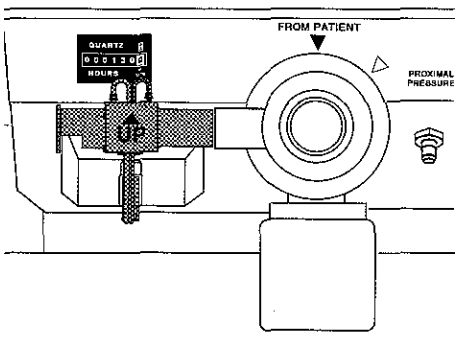
Insert the Diaphragm Mounting into the exhalation valve port by aligning the grooves with the notches in the port. To lock in the Diaphragm Mounting Base Assembly, press it in, and rotate clockwise. Locking enables the clinician to clean the exhalation valve without removing it from the ventilator. To remove a locked-in Diaphragm Mounting, press in the Mounting and rotate counterclockwise.

Attach the small 90cc condensate jar (P/N 50000-09901) to the exhalation valve manifold, checking for cracks or misthreadings which can cause a decrease in monitored exhaled volumes.



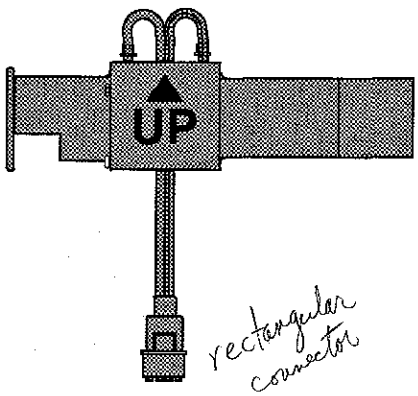
Place the manifold over the exhalation valve port and Diaphragm Mounting Base Assembly on the front of the ventilator. Be sure to align the arrow on the manifold with the outlined arrow printed adjacent to the exhalation valve port.

Press the manifold snugly against the ventilator, and rotate counter-clockwise until it stops at the solid arrow printed directly above the port. The condensate jar will be oriented downward.



Install the external flow sensor assembly as follows:

- Remove the BEAR® 1000 VarFlex® Flow Sensor from pack aging.
- Slide back the flow sensor/ventilator connector assembly locking sleeve.
- Plug the connector into the mating receptacle located on the left front face of the ventilator labeled "Flow Sensor." The connector assembly can only be installed one way. Next, slide the locking sleeve forward to secure.
- Install the VarFlex® Flow Sensor into the BEAR® 1000 Ventilator exhalation manifold with pressure sensing tubes and "arrow" pointing up.



CAUTION

Do not dry or clean the flow sensor with high pressure gas. Doing so will destroy the sensor. Follow the cleaning guidelines provided in Section 7.

CAUTION

The flow sensor must be installed with the pressure sensing tubes and arrow pointing up. Failure to do so may result in condensate accumulating in the tubes and affecting volume measurement.

ADULT CIRCUIT SETUP

Both adult and pediatric circuits can be used on your BEAR® 1000 Ventilator. Adult circuit assembly is shown in Figure 3-1, and that of a pediatric circuit in Figure 3-2.

When setting up an adult circuit, be sure to notice the proper orientation of the arrows on the two filters.

The 14-inch length of circuit tubing installed between the main-flow bacteria filter and the humidifier inlet may be exposed to high temperatures from the humidifier, particularly when ventilator flow and tidal volume settings are low. For this reason, it is advisable to install reusable rather than disposable tubing in this area. Heat from the humidifier may cause the disposable tubing to weaken or fail.

When installing a nebulizer in the circuit, attach 3/16" ID tubing to the nebulizer fitting. For details regarding nebulizer operation, refer to the *Panel Details & Specifications* (Section 5), where the NEBULIZER control key is described.

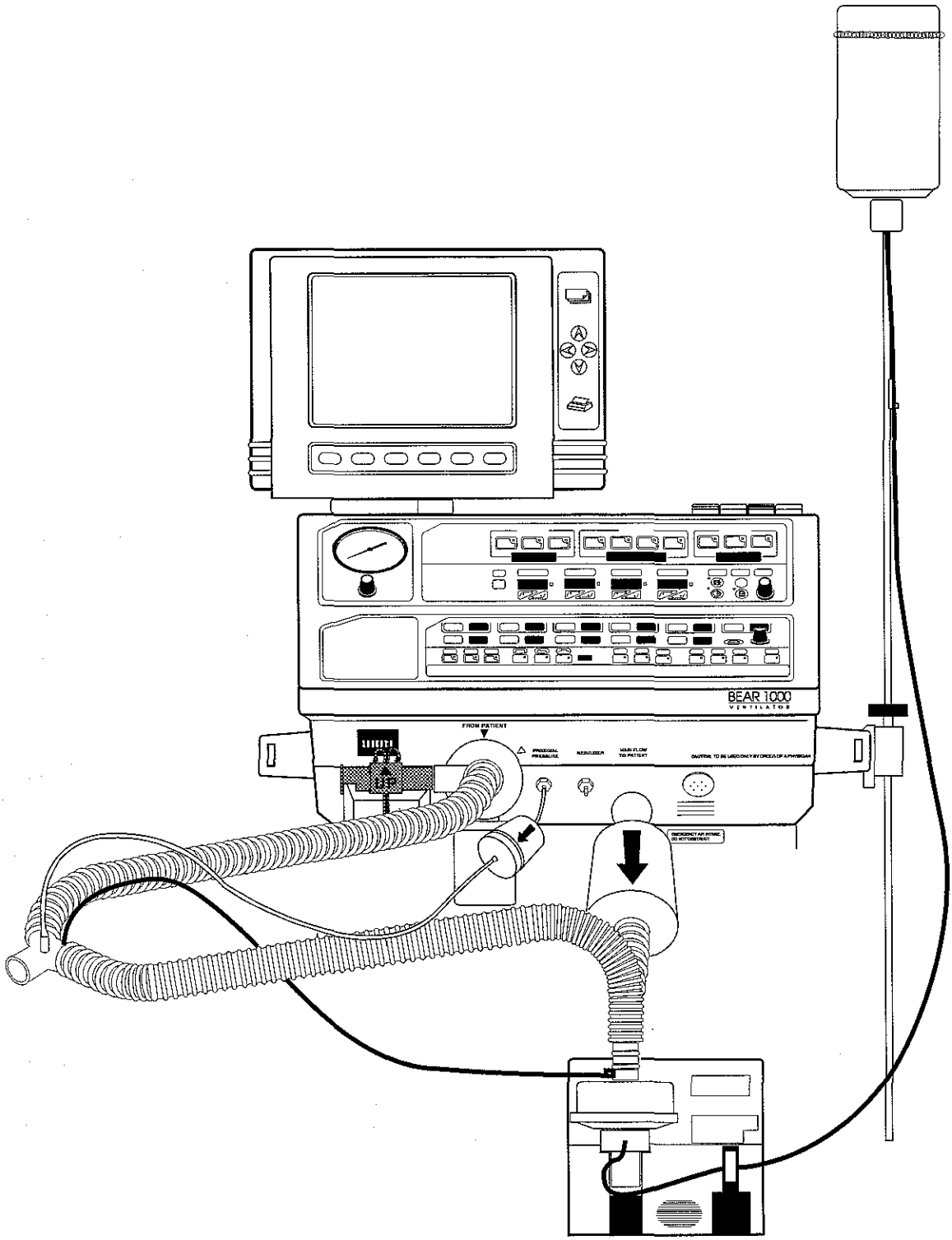


Figure 3-1 • Adult Circuit Assembly

If an in-line oxygen analyzer is used, install it in the circuit between the outlet of the ventilator (labeled "Main Flow to Patient") and the inlet of the mainflow bacteria filter.

WARNING

The proximal airway pressure monitoring line has a small purge flow; however it does not prevent water from entering the ventilator (as when a large bolus of water is accidentally drained toward the ventilator). If you suspect that water has entered the ventilator, refer the unit to an authorized service technician for verification.

The length, internal diameter and placement of the proximal airway pressure monitoring line is important. To maintain optimum sensitivity and performance, a 6-foot maximum 1/4" ID line must be securely placed at the the patient wye. The minimum ID of any adapter placed in-line should be 3/16" ID. Malfunction may result if a more restrictive adapter is placed in-line.

The blue Bear hydrophobic filter (P/N 50000-01106) may be used in a moist environment. Bear's white dry air filter (P/N 50000-01054) must not be used in a moist environment. Otherwise flow resistance may increase unacceptably, and the filter may even become occluded, thus inhibiting ventilation.

PEDIATRIC CIRCUIT SETUP

A pediatric circuit may be used with the BEAR® 1000 Ventilator. A pediatric circuit should be used in preference to an adult circuit when set tidal volumes are sufficiently small that volumes lost in the circuit become important.

Remember that whenever a patient has a pediatric circuit or an endotracheal tube size of less than the 5mm to 6mm range, the control setting for PRESSURE SLOPE should be adjusted into the Pediatric (P) range. Adjusting this control ensures the smooth delivery of all pressure breaths, even with the high resistance of the small ET tube sizes.

When setting up the circuit, be sure to notice the proper orientation of the arrows on the two filters.

The insertion of an adapter for a proximal temperature probe is optional. If no such probe is being used, this portion of the pediatric circuit setup can be omitted.

The warnings listed in the adult circuit setup also apply to pediatric circuits.

WARNING

The Pediatric Circuit setup must include the Tapered Flex Tube. Failing to do so may result in pressure fluctuation and injury to the patient.

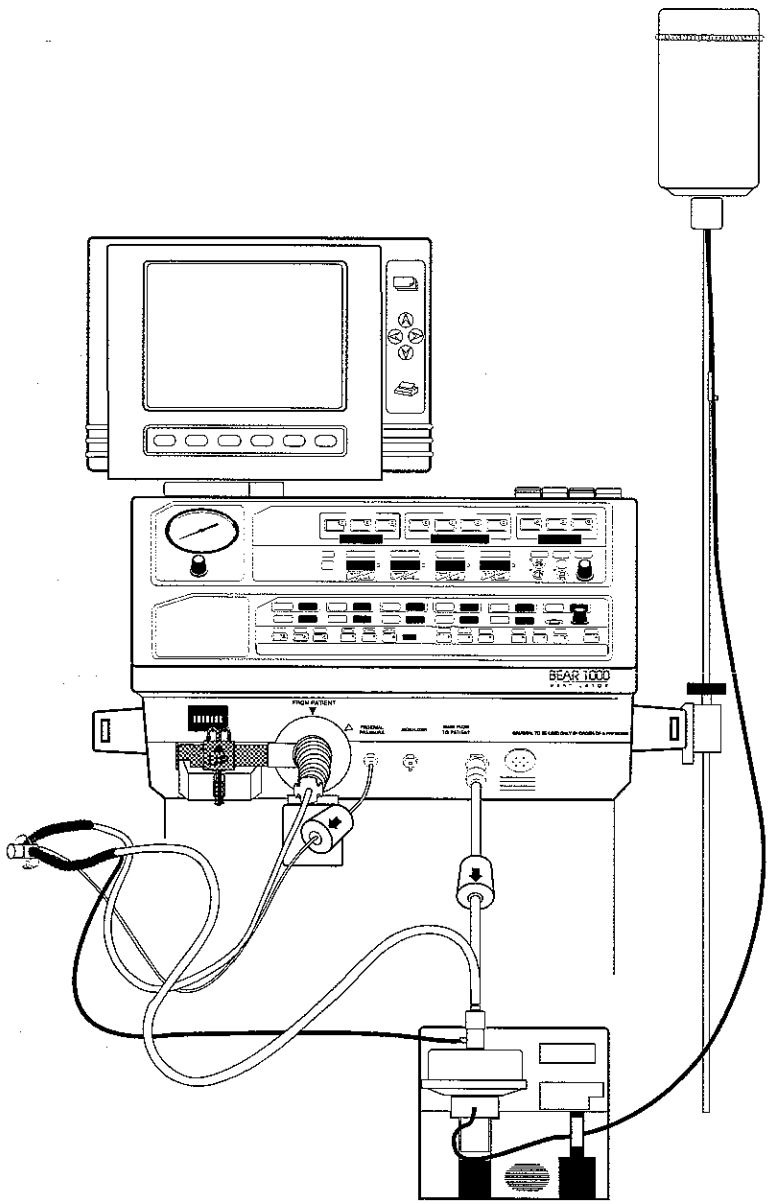


Figure 3-2 • Pediatric Circuit Assembly

The BEAR® 1000 Ventilator Pediatric Circuit Kit (Part Number 50000-01145) contains all the parts required to assemble a complete pediatric circuit (Figure 3-3). Use the illustration to assist in the pediatric circuit assembly.

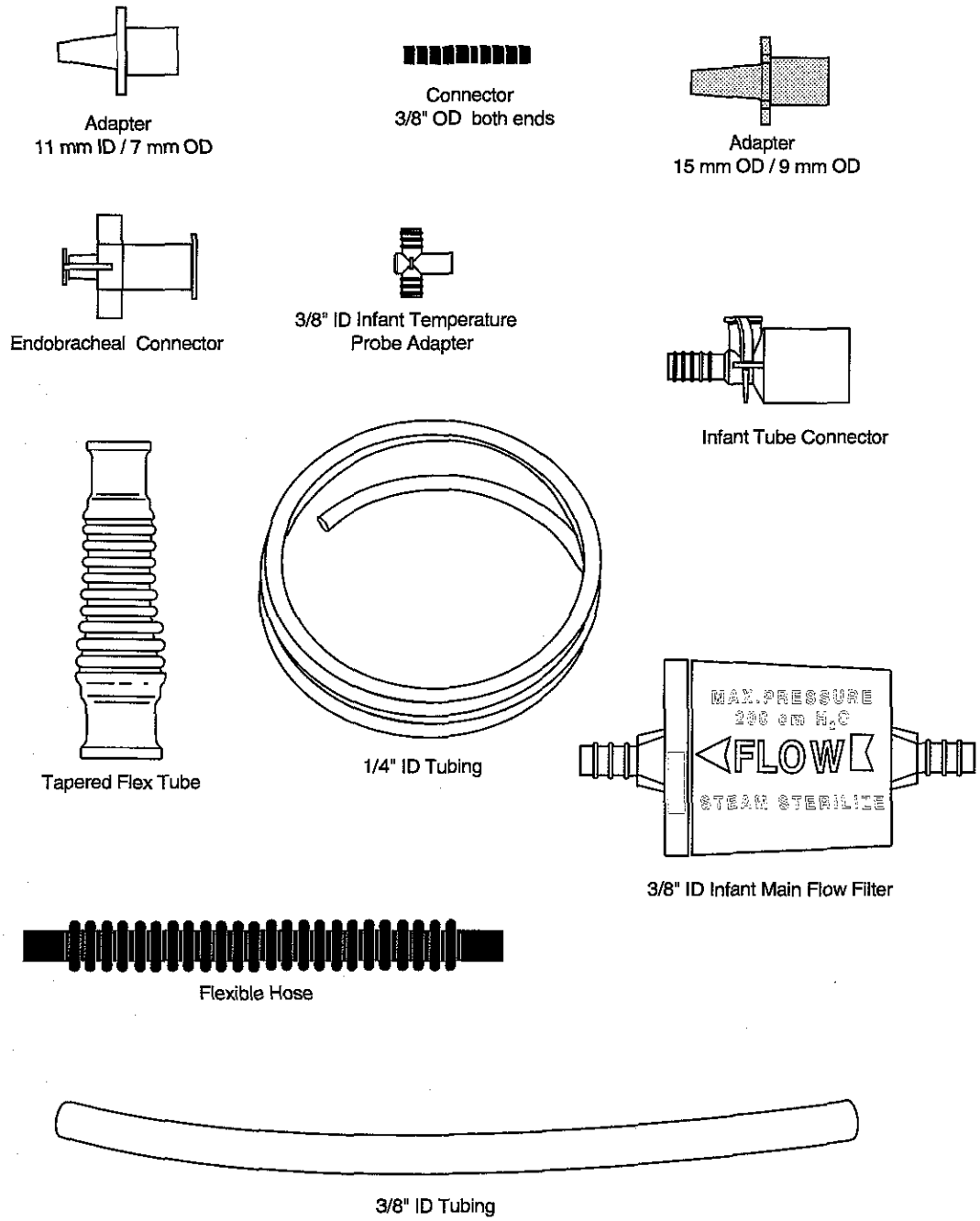


Figure 3-3 • Pediatric Circuit Kit Parts

QUICK OPERATIONAL CHECKOUT

Check out the unit with the help of the automated Quick Checkout. This sequence allows the clinician to confirm that the major subsystems of the ventilator are functioning properly. Perform this procedure prior to placing the ventilator on each new patient, or at least once a month.

Note that this automated test can only be performed when an adult circuit is attached. For pediatric circuits, first perform the following test with an adult circuit. Then install the pediatric circuit and perform a manual circuit leak test (step 9).

There are just a few simple steps involved in the automated Quick Checkout, they are as follows:

1) Ensure that the ventilator is connected to air and oxygen sources and plugged into A/C wall outlet prior to conducting the checkout.

2) Adjust the PEEP control level to zero by turning the PEEP knob (located adjacent to the analog manometer) completely counterclockwise.

NOTE

Make sure PEEP knob is fully counterclockwise, as manometer will always indicate zero.

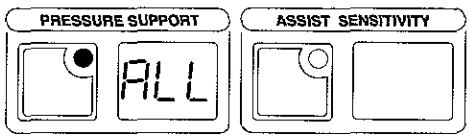
3) With an adult circuit attached, enter the Operator Diagnostics mode:

NOTE

A 72" Adult circuit must be used for the Automated Quick Checkout.

- Locate the TEST key on the front panel at the right side of the red Alarm Group.
- Press and hold this key while reaching to the right rear corner of the ventilator and turning on the power. Continue to hold the TEST key until the Diagnostics displays appear.

- Verify that the Operator Diagnostics mode is activated by observing the RUN DIAGNOSTICS LED illuminates.



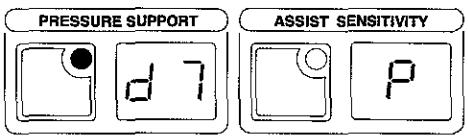
4) Notice that "ALL" appears in the PRESSURE SUPPORT DISPLAY located in the green Control Group. "ALL" means that the checkout procedure will perform all seven tests described in Section 7 of this manual.

   If "ALL" does not appear in the LED display, press the PRESSURE SUPPORT key, observe its LED display flash, and turn the green control SET knob until "ALL" does appear.

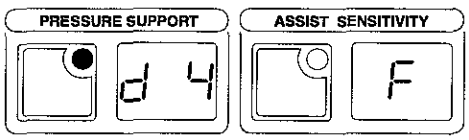
5) Plug off the patient wye. (Do Not Use a test lung)

6) Press the MANUAL BREATH key located in the lower center of the green Control Group. The automated test will begin and last approximately 2 1/2 minutes.

   To cancel the test before it is complete, press the EXPIRATORY HOLD key.



7) When all of the checkout tests pass, the display appears as shown. The "P" stands for "Pass".



8) If one of the seven tests fails, the checkout stops at that test. The number designation for the failed test appears in the PRESSURE SUPPORT display and the letter "F" for "Fail" appears adjacent to the test number in the ASSIST SENSITIVITY display. A d4 failure most likely indicates a circuit or exhalation valve leak. Such a leak can usually be corrected by the operator. A d7 failure is normally related to not using a 72" circuit for the checkout or not turning the PEEP control knob full counterclockwise. Refer to Section 7 for a description of each of the other tests.

   If a diagnostic test failure occurs, restart the "ALL" test by pressing the MANUAL BREATH key.

WARNING

If the unit continues to fail the Quick Checkout, it should be referred to an authorized service technician. DO NOT use the ventilator on a patient.

9) When using a pediatric circuit, a manual leak test should be performed after the pediatric circuit is attached. Place the ventilator in the normal operating mode to conduct this test.

Connect a test lung with a compliance of 10 ml/cmH_2O to the pediatric circuit. (If a Manley test lung is used, set the resistance at 5. If a rubber test lung is used, be sure to simulate some resistance by including a 7mm adapter such as that on an endotracheal tube.) Adjust the ventilator settings as follow:

PEAK INSP PRESSURE Alarm	120 cmH_2O
TIDAL VOLUME	0.70 L
RATE	10 BPM
PEAK FLOW	30 LPM
PRES SUP/INSP PRES	0 cmH_2O
ASSIST SENSITIVITY	5.0 cmH_2O
† INSPIRATORY PAUSE	2.0 sec
COMPLIANCE COMP	0.0 ml/cmH_2O
MODE	ASSIST CMV
WAVEFORM	square

† Use the manual inspiratory pause key on those configurations which do not feature the inspiratory pause function.

During the inspiratory pause of each breath, the pressure should not drop more than 10 cmH_2O.

POWERING UP

To power up in the normal operational mode, turn off the power to exit Operator Diagnostics. Now, turn on the power, without pressing the TEST key.

At power up, the ventilator performs an automatic, 12-second electronic self-check to verify correct operation of the electronic hardware. After this brief self-check, the ventilator is ready to ventilate. Press ALARM SILENCE to stop the audible tone.

NOTE

During the Power up sequence, the front panel LEDs are dimmed for lower power consumption.

CIRCUIT/ALARMS CHECKOUT

Ensure that the ventilator is connected to air and oxygen sources and plugged into A/C wall outlet prior to conducting the Circuit/Alarms Checkout procedure.

1. Install an Adult Breathing Circuit onto the ventilator (see Fig. 3-1) and attach a Manley Test Lung (P/N 50012-20102) or equivalent onto the patient circuit.

2. Turn the ventilator power switch (located on the rear panel) to the "ON" position.

NOTE

Upon power up, the ventilator performs an automated 12 second self-check to verify correct operation of the internal electronics. After completion of the self-check, press the ALARM SILENCE to stop the audible tone.

3. Adjust the controls and alarms as follows:

CONTROLS	SETTINGS
Mode	Assist CMV
Tidal Volume	0.5 Liters
Rate	12 BPM
Peak Flow	40 LPM
02%	40 %
Pressure Support	0
Assist Sensitivity	5.0 cmH2O
PEEP/CPAP	5 cmH2O
Waveform	Square
Base Flow	0
Pressure Augment	"OFF"
ALARMS	
Total Minute Volume	
• High	7.0 Liters
• Low	5.0 Liters
Total Breath Rate	
• High	16 BPM
• Low	8 BPM
Peak Inspiratory Pressure	
• High	10 cmH2O above measured Peak Pressure
• Low	10 cmH2O below measured Peak Pressure
Baseline Pressure	
• High	10 cmH2O
• Low	2 cmH2O

4. With the ventilator cycling and the alarms limit set, disconnect the test lung from the circuit. Verify that the LOW BASELINE PRESSURE and LOW PEAK INSPIRATORY PRESSURE alarms activate and the audible alarm is detected. Reconnect the test lung and allow the audible alarm to self cancel, then press VISUAL RESET to clear.

5. Set the ventilator rate to zero and verify that the LOW TOTAL MINUTE VOLUME and LOW TOTAL BREATH RATE alarms activate and the audible alarm is detected. Adjust the ventilator rate back to 12 BPM to cancel the audible alarm, then press VISUAL REST to clear.

6. Increase the delivered Tidal Volume as required to cause the Peak Inspiratory Pressure to go above the high limit alarm and note the following:

   - HIGH PEAK INSPIRATORY PRESSURE visual alarm activates
   - Audible alarm sounds
   - Breath delivery is terminated at alarm limit setting

   Return the Tidal Volume to 0.5 Liters to cancel the audible alarm, then press Visual Reset to clear.

7. Disconnect the ventilator power cord from the wall and verify that an audible alarm is activated. Reconnect the power cord to the wall and following the 12 second power up self check, press the alarm silence to stop the audible alarm.

8. The checkout is now complete.

WARNING

If a mechanical or electrical problem is recognized while running the Circuit Checkout Procedure, or while operating the ventilator, the ventilator must be removed from use and referred to qualified personnel for servicing. Using an inoperative ventilator may result in patient injury.

COMPLIANCE COMPENSATION FACTORS

Some models of the BEAR® 1000 Ventilator possess the ability to compliance compensate.

A prerequisite for using this feature is that the compliance factor be determined prior to placing the ventilator on a patient.

Some disposable circuits have a known compliance factor. If this is true of your circuit, as well as of other in-line devices,

add the known compliance values and use the sum for COMPLIANCE COMP (in units of ml/cmH_2O) when setting up a ventilatory mode.

For pediatric circuits, use a standard compliance factor (typically 1 to 1.5 ml/cmH_2O).

The BEAR® 1000 Ventilator is now set to automatically compensate for volumes lost due to circuit compliance. Refer to the *Panel Details & Specifications* (Section 5) for a complete description of the COMPLIANCE COMP key.

4. OPERATION

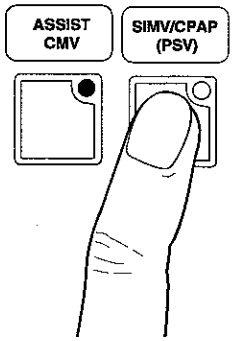
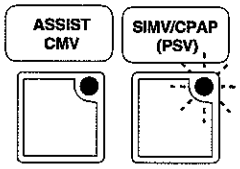
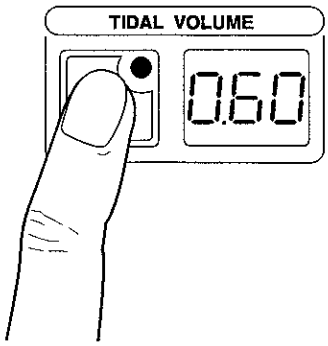
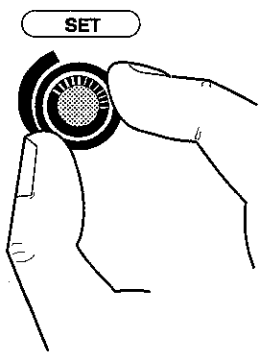
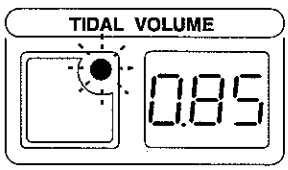
OVERVIEW

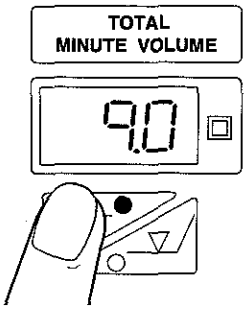
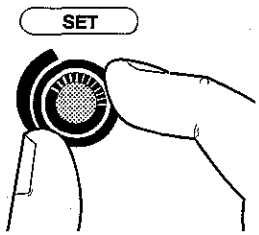
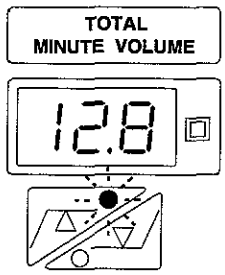
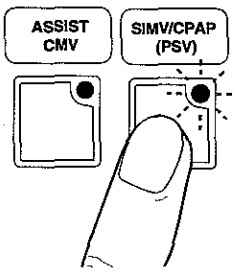
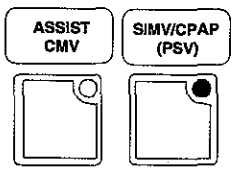
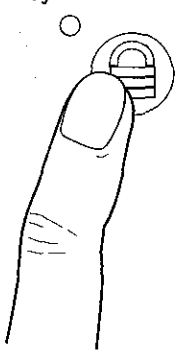
The following pages describe how to initiate and adjust a mode on the BEAR® 1000 Ventilator. Following the general mode setup description, a description of the fundamentals of each mode is provided for more in-depth understanding.

GENERAL MODE SETUP

The following diagram depicts the methodology for setting up any ventilatory mode. While this example illustrates SIMV, setup methodology is the same regardless of whether the mode is Assist CMV, SIMV, CPAP, Pressure Control or PC-SIMV (see Table 4-A on next page).

Table 4-A
General Mode Setup

ACTION	RESULT	COMMENTS
1. Press the key for the new mode. 		Observe the key LED flash for the newly proposed mode. Observe that the original mode key continues to be lit and continues to operate. Observe that the control panel displays only those controls which are available in the newly proposed mode. (Any control with a lighted key LED is available in the proposed mode.)
2. Adjust the controls by pressing each key, and then ...  turning the green Control SET knob. 		Adjust each available control as appropriate. Each control setting change becomes effective immediately. So, if a control is being used in the currently operating mode, a change in its setting will cause an immediately effective change in ventilation. The PRESSURE SLOPE control should first be set to zero ("0")—or "P0" when used with a pediatric circuit. To further fine-tune this control for maximum patient comfort, use a graphic display of the pressure waveform, and refer to the *Panel Details & Specifications* section for a description of this key.

ACTION	RESULT	COMMENTS
3. Adjust the alarms by pressing each key, and then... turning the red Alarm SET knob.  		Adjust all alarms (both high and low) as appropriate. Remember to re-assess the alarm settings after a few minutes, once the patient becomes accustomed to the new mode.
4. Activate the mode by pressing the flashing mode key. 		To commence operating in the newly proposed mode, press the flashing mode key once again. If the clinician does not enter the new mode within one minute of the last setting change, the proposed mode key will stop flashing, and ventilation will continue in the original mode.
5. Press the Alarm and Control Lock keys. 		*Optional.* To prevent inadvertent changes in ventilator settings, press the Alarm LOCK and the Control LOCK keys.

CONTROL OPTION AVAILABILITY BY MODE

Some controls are not applicable, and therefore not available, in every ventilatory mode. The available controls can be recognized during ventilator operation since the corresponding key LED is lit. Thus, a lighted key LED indicates a control is available in the current mode.

ASSIST CMV Setup

Entering the Assist CMV mode is described at the beginning of this section.

ASSIST CMV Fundamentals

A volume breath is delivered when:

- a breath time period elapses, as determined by the RATE control setting, or
- when the patient activates the assist trigger.

Provided the clinician-set ASSIST SENSITIVITY threshold is met, the patient may trigger every breath if demand exceeds the set RATE, resulting in a synchronization of mechanical breaths with patient demand. If the patient does not trigger a breath before the time period elapses, the ventilator will deliver a mandatory volume-controlled breath according to the clinician-selected TIDAL VOLUME, RATE, and PEAK FLOW, as illustrated.

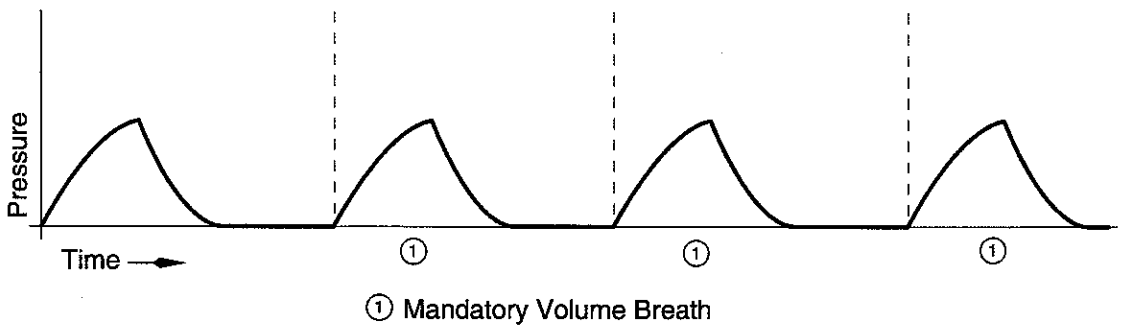


Figure 4-1 • Assist CMV Pressure Graphic—No Patient Triggering

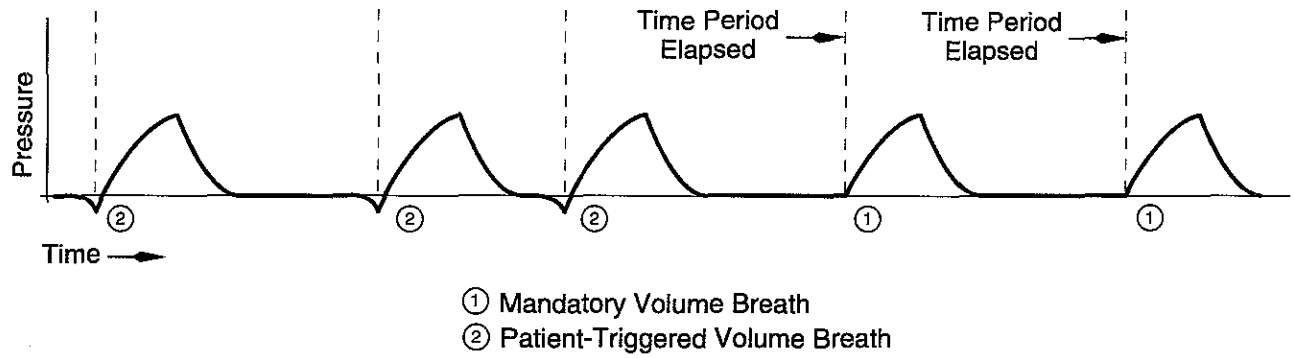


Figure 4-2 • Assist CMV Pressure Graphic—with Some Patient Triggering

SIMV Setup

Entering the SIMV mode is described at the beginning of this section.

SIMV Fundamentals

In this mode, both volume-controlled and spontaneous (or pressure supported) breaths can occur. Between volume-controlled (or pressure supported) breaths, patient-controlled breaths may occur. Blended gas for these spontaneous breaths is supplied by the demand system, which is capable of providing more than 200 LPM of flow.

The concept of an "assist window" is very useful when describing the fundamentals of SIMV operation.

When a volume-controlled breath is due (as determined by the RATE control), the assist window opens and waits for the patient's inspiratory effort. Upon sensing the patient's inspiratory effort, the ventilator delivers the preset TIDAL VOLUME at the preset PEAK FLOW and wave pattern. As soon as the single volume-controlled breath has been triggered, the assist window closes. As a consequence, once the volume-controlled breath has been delivered, subsequent patient effort results only in spontaneous (or pressure supported) breaths until the next mandatory breath is due.

If the patient has a period of apnea and the assist window does not see an inspiratory effort on the part of the patient, a mandatory breath will be delivered at the beginning of the next breath time period. Mandatory breaths will continue according to the respiratory rate set on the RATE control until the next inspiratory

effort from the patient is sensed. If an apneic period causes the monitored breath rate to be less than the clinician-set low TOTAL BREATH RATE alarm setting, the audible and visual alarm will activate and "AP" will appear in the alarm window.

SIMV With Pressure Support

The BEAR® 1000 Ventilator offers pressure support from 0 to 80 cmH_2O. In SIMV with pressure support, volume-controlled breaths are delivered according to the clinician-set TIDAL VOLUME, RATE, and PEAK FLOW. The remaining demand efforts are pressure-supported.

A pressure-supported breath is triggered when the patient's inspiratory effort meets or exceeds the ASSIST SENSITIVITY threshold. Flow to the patient circuit is increased to raise and maintain the inspiratory pressure at the preset PRESSURE SUPPORT controL level plus baseline (PEEP). For example, if PEEP is set at 5 cmH_2O and PRESSURE SUPPORT control is set at 20 cmH_2O, the pressure-supported breath will rise to 25 cmH_2O.

When inspiratory flow decreases to approximately 30% of the peak flow, inspiration terminates and the exhalation valve opens. During exhalation, the pressure in the patient circuit returns to baseline (PEEP level). All pressure-supported breaths are completely controlled by the patient with respect to breath rate, tidal volume, peak flow and flow waveform characteristics.

If a leak occurs during a pressure-supported breath preventing flow from decreasing to approximately 30% of the peak flow, inspiration will terminate after 5 seconds.

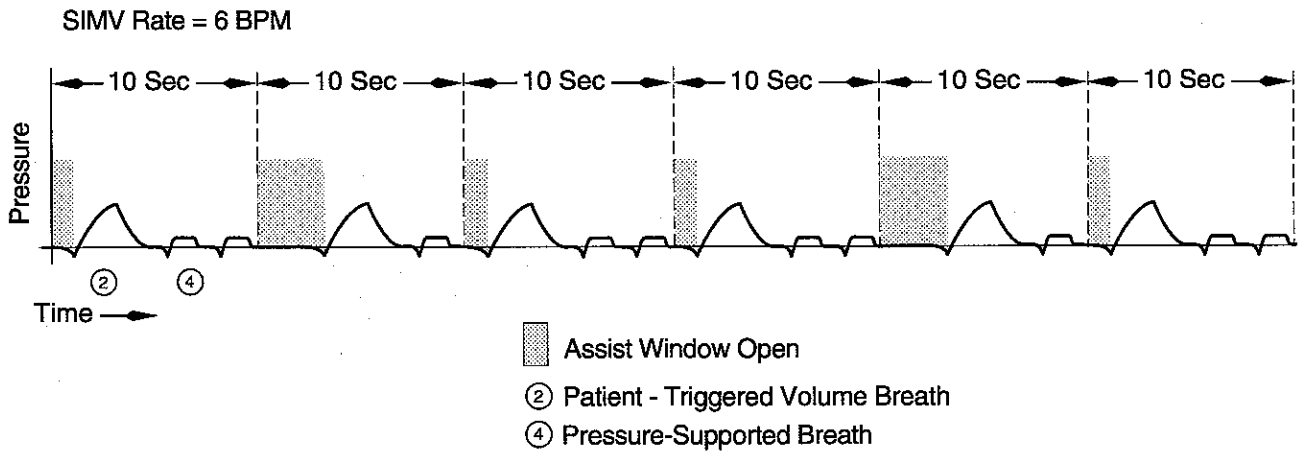


Figure 4-3 • SIMV Pressure Graphic—with Pressure Support

CPAP Setup

While SIMV and CPAP are accessed with the same mode key, the distinction between them lies with the RATE control. When RATE is set to zero, the ventilator is in the CPAP mode. If RATE is anything above zero, the ventilator is in the SIMV mode.

While all of the same controls which are available in SIMV are also available in CPAP, many of them are not used by the ventilator in CPAP unless certain conditions exist. For example, TIDAL VOLUME is available, yet it is not normally used during CPAP. However, there are three conditions where TIDAL VOLUME is, in fact, used during CPAP, as follows:

1) a MANUAL BREATH is delivered,

2) a MANUAL BREATH is triggered and SIGHS are "on", or

3) the MMV LEVEL control is set above zero.

In any of these circumstances, a volume-controlled breath would (or could) be delivered, and the current control setting for TIDAL VOLUME would then determine the breath's volume. Since a volume-controlled breath could be delivered in CPAP, select appropriate levels for all available settings even if these settings are not being routinely used.

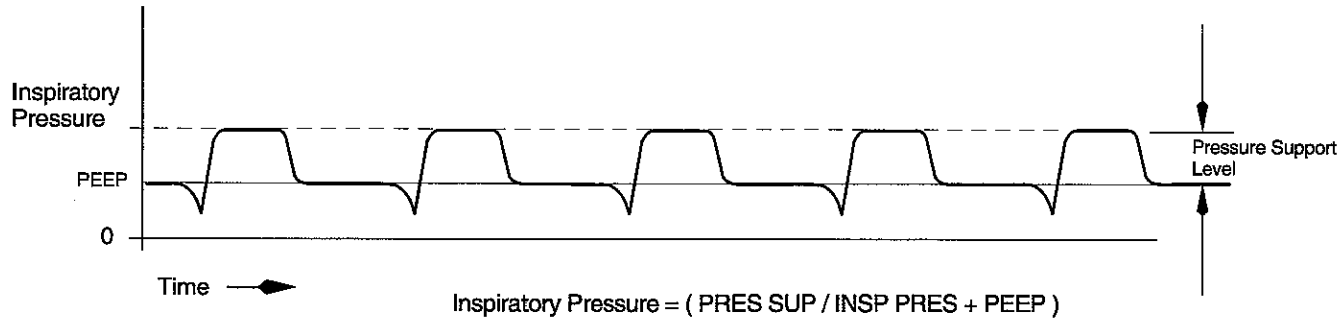
CPAP Fundamentals

In CPAP, the patient breathes spontaneously, and all breaths are counted by the RATE monitor when patient effort meets or exceeds the ASSIST SENSITIVITY threshold. In addition, a constant airway pressure is maintained throughout the breath cycle, as determined by the clinician-selected PEEP level. The PRESSURE SLOPE control affects the rate of flow response during spontaneous breaths. Higher PRESSURE SLOPE settings yield faster response times.

CPAP With Pressure Support

Pressure support ventilation (PSV) is available in the CPAP mode by adjusting the PRESSURE SUPPORT control to the desired setting. When the patient's inspiratory effort meets or exceeds the ASSIST SENSITIVITY setting, a pressure-supported breath is triggered.

The baseline (PEEP) pressure may be adjusted from zero to 50 cmH_2O, with the caveat that the sum of PEEP plus PRESSURE SUPPORT cannot exceed 120 cmH_2O, the maximum allowable circuit pressure.



4-4 • CPAP Pressure Graphic—with Pressure Support

MMV

The BEAR® 1000 Ventilator can ensure that spontaneously breathing patients in the SIMV and CPAP modes receive a Minimum Minute Volume.

When using MMV, four parameters interact and distinguish this feature from a pure SIMV or CPAP mode. These parameters are:

- TIDAL VOLUME
- RATE
- MMV LEVEL
- Monitored Total Exhaled Minute Volume

As long as the monitored total exhaled minute volume meets or exceeds the clinician-set minimum minute volume and an APNEA alarm is not active, backup ventilator support is inactive.

However, if the monitored total exhaled minute volume falls below the desired level or an APNEA alarm occurs, the MMV LEVEL control causes the breath rate to automatically increase to ensure that the minimum minute volume is delivered.

The MMV backup breath rate is determined as follows:

$$\text{Backup Rate (BPM)} = \frac{\text{MMV LEVEL (L/min)}}{\text{TIDAL VOLUME (L/breath)}}$$

During operation at the MMV backup rate, the patient is still able to trigger spontaneous or pressure supported breaths and to receive synchronized volume-controlled breaths.

The ventilator will return to operation at the clinician-set RATE, when the monitored total exhaled minute volume exceeds the clinician-set MMV LEVEL by 1 LPM or 10%, whichever is greater, and an assist trigger or manual breath is detected.

WARNING

Remember that the minimum minute volume must be set to a value greater than the clinician-set (RATE) x (TIDAL VOLUME). If it is set to a lower value, MMV operation will not be effective.

The MMV ACTIVE indicator illuminates during inspiration and exhalation whenever the MMV backup rate is active. The MMV % monitor displays the percentage of time during the last half-hour that the MMV backup rate has been in use instead of the normal, clinician-set RATE.

WARNING

While using MMV, set the high TOTAL BREATH RATE alarm appropriately to minimize the risk associated with tachypnea and to detect the fast shallow breathing of patients in respiratory distress due to fatigue, anxiety, pain, or hypoxcia.

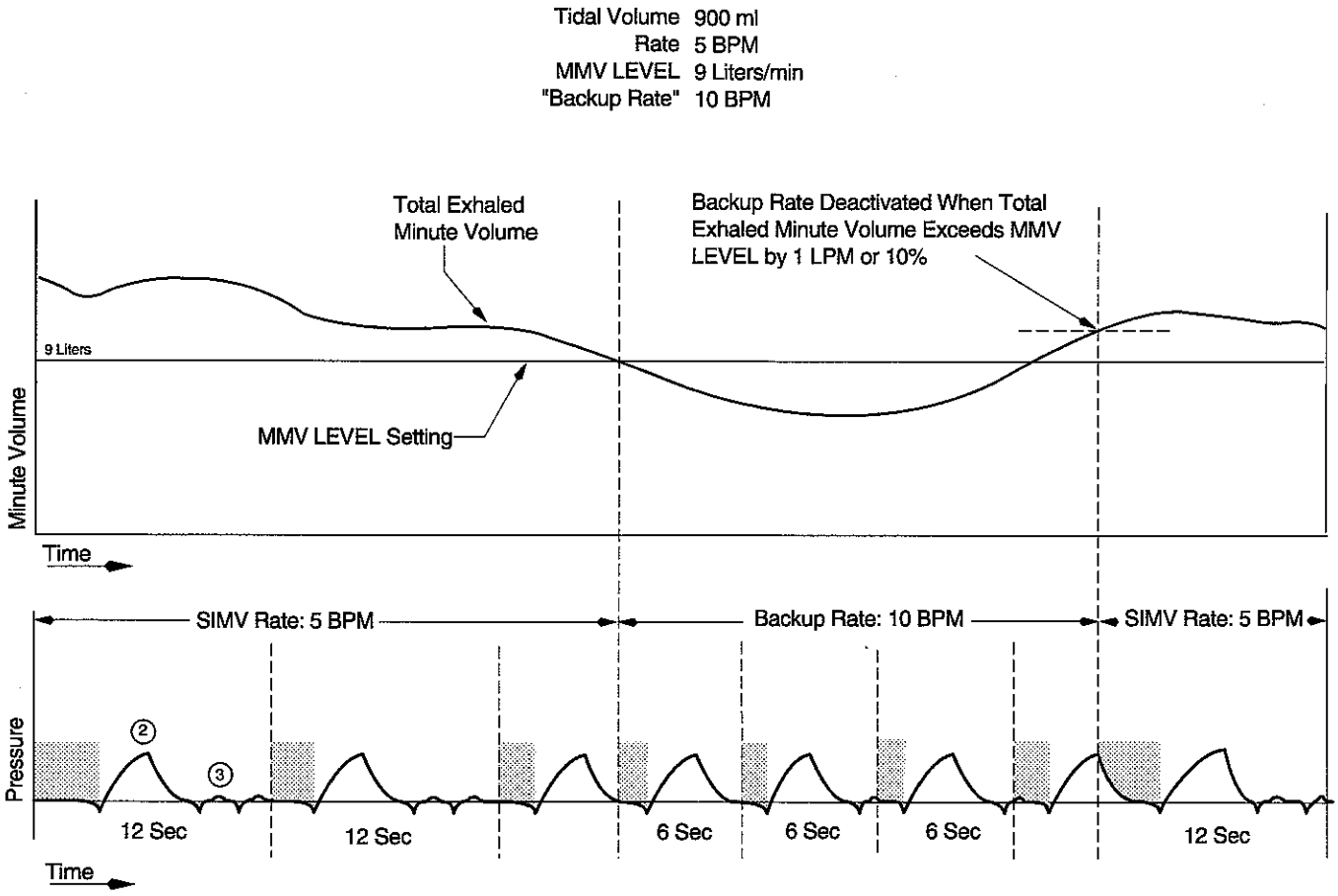


Figure 4-5 • MMV Operation During SIMV

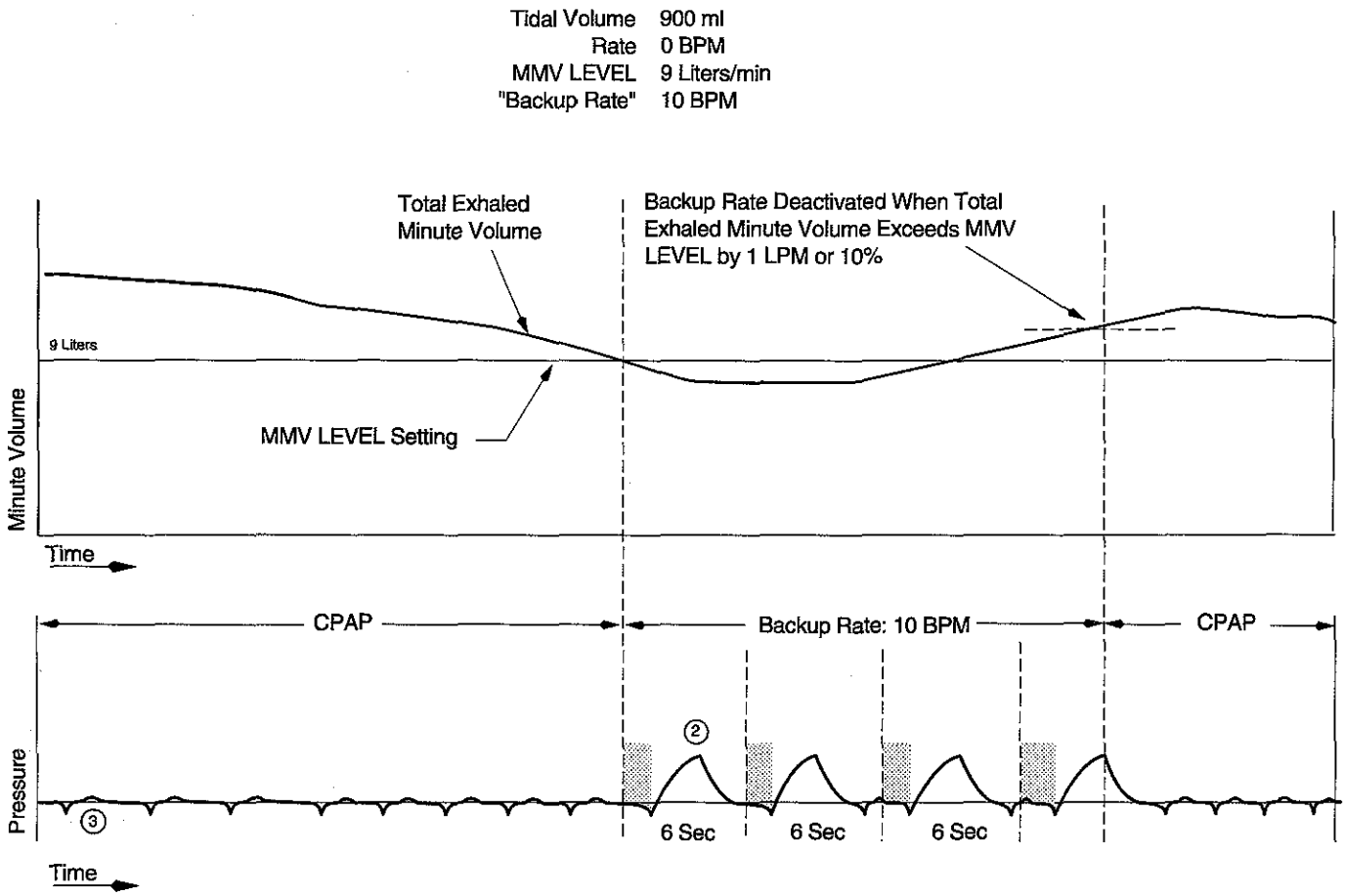


Figure 4-6 • MMV Operation During CPAP

PRESSURE CONTROL Setup

The Pressure Control mode is set up in the same fashion as any other mode. Follow the general mode setup guidelines provided at the beginning of this section.

CAUTION

Be sure to set the high PEAK INSPIRATORY PRESSURE alarm to protect the patient from pressure rises caused by a cough.

NOTE

The INSPIRATORY PRESSURE control determines the inspiratory pressure level during operation in the pressure control mode. This control also serves a separate but related function in establishing the target pressure for augmented breaths.

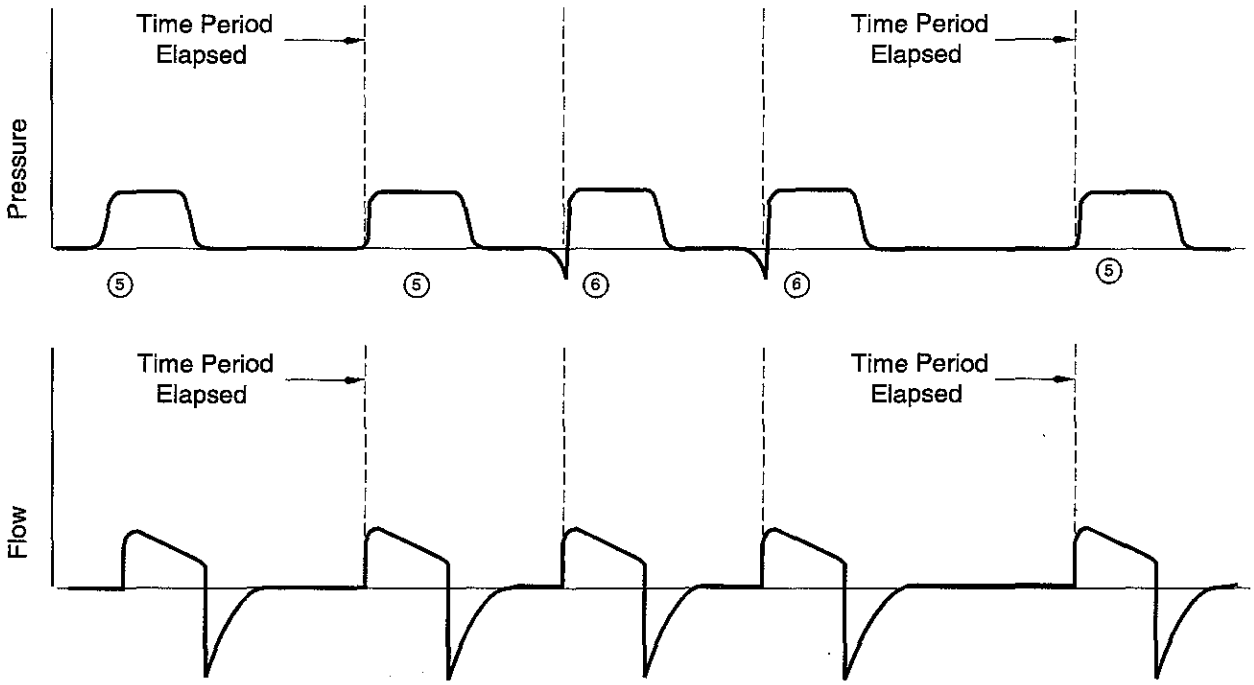
PRESSURE CONTROL Fundamentals

The Pressure Control mode delivers breaths to the patient at a constant inspiratory pressure during the set inspiratory time. The volume delivered to the patient is dependent upon the clinician-set INSPIRATORY PRESSURE LEVEL, INSPIRATORY TIME AND RATE. In addition, the volume may vary due to change in the patient's airway resistance and lung compliance.

A pressure-controlled breath is initiated when either the breath time period elapses (as determined by the breath RATE control setting) or the patient's effort meets or exceeds the ASSIST SENSITIVITY threshold. Enough flow is delivered to pressurize the patient circuit to the sum of inspiratory pressure plus baseline (PEEP). For example, if the INSPIRATORY PRESSURE control is set at 20 cmH_2O and peep is 10 cmH_2O, the total inspiratory pressure level of a pressure-controlled breath is 30 cmH_2O.

Flow continues to be delivered to maintain pressure for the duration of the preset INSPIRATORY TIME. Breath delivery terminates when the preset INSPIRATORY TIME elapses. During exhalation, pressure returns to the preset PEEP level.

The breath time period is reset at the start of every pressure-controlled breath. Therefore, the patient may trigger every breath when breathing faster than the preset breath RATE. On the other hand, without triggering any breaths, the patient receives mechanical breaths at the preset RATE.



⑤ Machine –Triggered, Pressure Breath
⑥ Patient–Triggered, Pressure Breath

Figure 4-7 • Pressure Control Pressure and Flow Graphic

WARNING

Unlike operation in Assist CMV or SIMV, when operating in the Pressure Control mode, tidal volumes are not clinician settable. Accordingly, be sure to establish appropriate TOTAL MINUTE VOLUME and TOTAL BREATH RATE alarm settings.

With the BEAR® 1000 Ventilator, the clinician may also institute pressure control with inverse ratio ventilation (PC-IRV). To use PC-IRV, the clinician must activate the I:E OVERRIDE key located in the red Alarm Group. When the built-in 1:1 limit is overridden, the ventilator allows up to 4:1 ratio ventilation.

WARNING

Auto-PEEP is not always accurately measured by a proximal pressure reading during mechanical ventilation. This is particularly true during PC-IRV where lung pressure and circuit pressure may not reach equilibrium prior to the initiation of a new breath. The short expiratory times associated with Inverse Ratio Ventilation may result in incomplete exhalation and, as a consequence, lead to gas trapping (Auto-PEEP) and patient compromise.

PC-SIMV Setup

The PC-SIMV mode is set in the same manner as any other mode. Follow the general mode setup guidelines provided at the beginning of this section.

PC-SIMV Fundamentals

In this mode, both pressure-controlled and spontaneous breaths can occur. Pressure-controlled breaths are delivered at a constant inspiratory pressure for a specific inspiratory time while spontaneous breaths are patient regulated.

When a pressure-controlled breath is due (as determined by the RATE control), the assist window opens and waits for the patients inspiratory effort. If the patient effort meets or exceeds the ASSIST SENSITIVITY threshold, then enough flow is delivered to pressurize the patient circuit to the sum of inspiratory pressure plus PEEP. For example, if the INSPIRATORY PRESSURE control is set at 20 cmH2O and PEEP is 10 cmH2O, the total inspiratory pressure level for the pressure-controlled breath will be 30 cmH2O. As soon as the single pressure-controlled breath has been triggered, the ASSIST window closes. Now in inspiration, flow continues to be delivered to maintain pressure for the duration of the preset inspiratory time. Breath delivery terminates when the preset INSPIRATORY TIME elapses. During exhalation, pressure returns to the preset PEEP level.

Following delivery of the pressure-controlled breath, subsequent patient efforts result only in spontaneous breaths (non pressure-controlled) until the next mandatory breath is due.

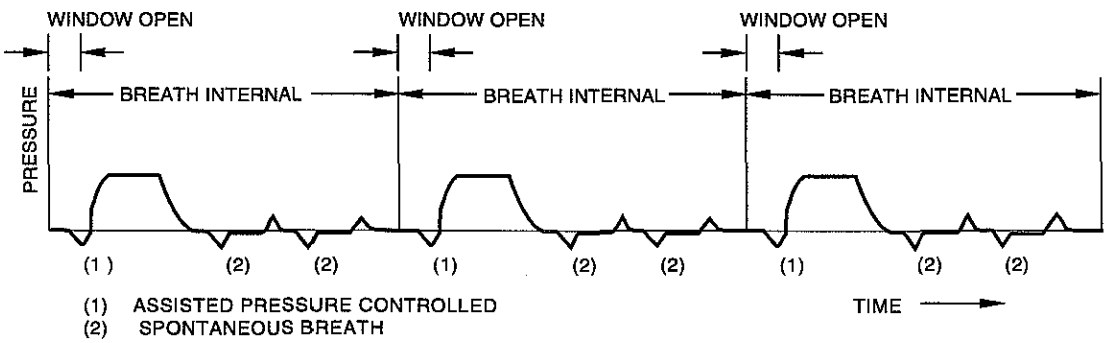


Figure 4-8 • PC-SIMV Pressure Graphic

PC-SIMV With Pressure Support

PC-SIMV with pressure support operates identical to PC-SIMV, except that the demand breaths are pressure-supported breaths.

A pressure-supported breath is triggered when the patient's inspiratory effort meets or exceeds the ASSIST SENSITIVITY threshold. Flow to the patient circuit is increased to raise and maintain the inspiratory pressure at the preset pressure support level plus baseline (PEEP). For example, if PEEP is set at 5 cmH2O and PRESSURE SUPPORT is set at 20 cmH2O, the pressure-supported breath will rise to 25 cmH2O.

When inspiratory flow decreases to approximately 30% of the peak flow, inspiration terminates and the exhalation valve opens. During exhalation, the pressure in the patient circuit returns to baseline (PEEP). All pressure-supported breaths are completely controlled by the patient with respect to breath rate, tidal volume, peak flow, and flow waveform characteristics.

NOTE

If a leak occurs during a pressure-supported breath preventing flow from decreasing to approximately 30% of the peak flow, inspiration will terminate after 5 seconds.

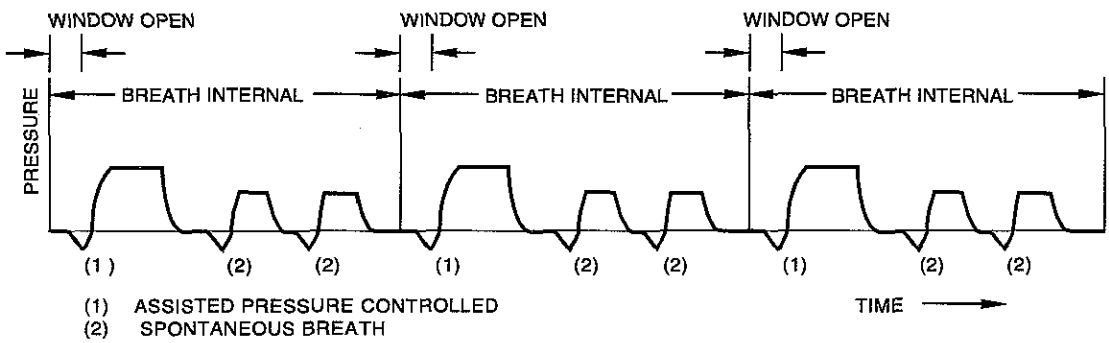


Figure 4-9 • PC-SIMV Pressure Graphic (Pressure Support)

CPAP Setup

While PC-SIMV and CPAP are accessed with the same mode key, the distinction between them lies with the RATE control. When RATE is set to zero, the ventilator is in the CPAP mode. If RATE is anything above zero, the ventilator is in the PC-SIMV mode.

CPAP Fundamentals

In CPAP, the patient breathes spontaneously, and all breaths are counted by the RATE monitor when patient effort meets or exceeds the ASSIST SENSITIVITY threshold. In addition, a constant airway pressure is maintained throughout the breath cycle, as determined by the clinician-selected PEEP level. The PRESSURE SLOPE control affects the rate of flow response during spontaneous breaths. High PRESSURE SLOPE settings yield faster response times.

CPAP Pressure Support

Pressure support ventilation (PSV) is available in the CPAP mode by adjusting the PRESSURE SUPPORT control to the desired settings. When the patient's inspiratory effort meets or exceeds the ASSIST SENSITIVITY settings, a pressure-supported breath is triggered.

The baseline (PEEP) pressure may be adjusted from zero to 50 cmH2O, but the sum of PEEP plus pressure support cannot exceed 120 cmH2O, maximum allowable circuit pressure.

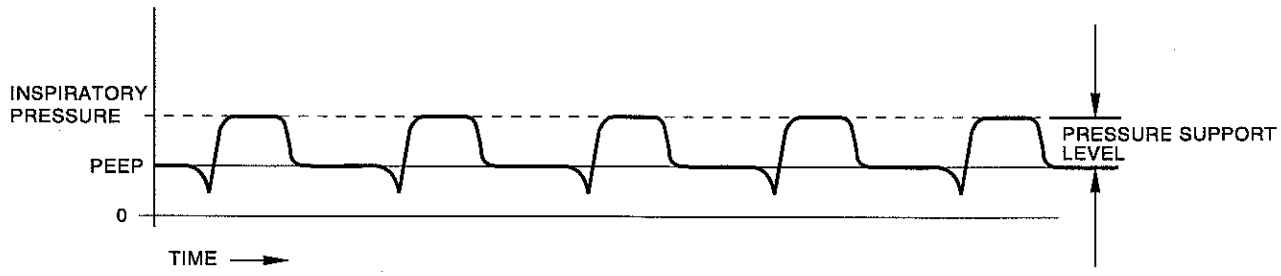


Figure 4-10 • Inspiratory Pressure = (Pressure Support + PEEP)

PRESSURE AUGMENTATION Setup

Pressure Augmentation offers both the ventilator-patient synchrony effects of pressure ventilation together with the volume guarantee effects of volume ventilation.

Pressure Augmentation can be used in conjunction with any mode where volume breaths are delivered—during Assist CMV, as well as during SIMV. Once PRESSURE AUGMENT is enabled, all breaths that would have been "volume-controlled" in these modes now become "volume-guaranteed."

To operate Pressure Augmentation:

1) Adjust the INSPIRATORY PRESSURE control to a desired level above baseline.

2) Select the minimum tidal volume guarantee by setting TIDAL VOLUME accordingly.

3) Press the PRES AUGMENT control to activate the feature.

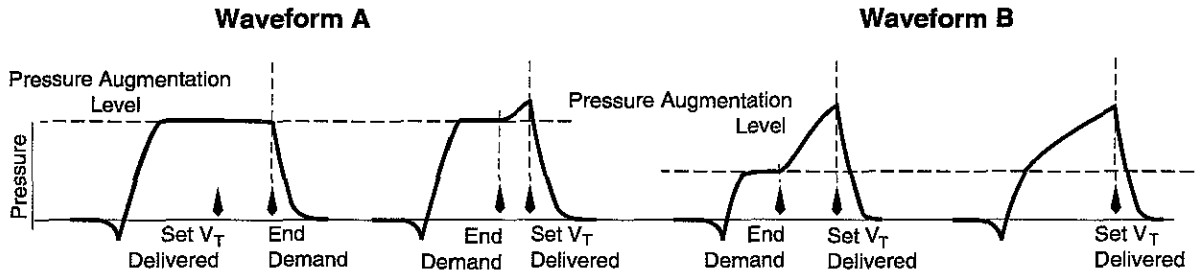
4) Adjust the high PEAK INSP PRESSURE alarm appropriately.

PRESSURE AUGMENTATION Fundamentals

Pressure Augmentation combines the benefits of both pressure and volume ventilation. It offers:

- The superior assist synchrony effects of pressure ventilation where flows can more closely match patient demand, thereby reducing imposed loads, and
- The tidal volume guarantee effects of volume ventilation.

Depending upon the clinician's settings for INSPIRATORY PRESSURE in relation to the PEAK FLOW and guaranteed TIDAL VOLUME settings, the graphical ventilatory pattern during pressure augmentation can vary widely. These settings interact with one another and with the patient's demand, compliance and resistance to yield anything from a typical pressure breath graphical pattern (waveform A, Figure 4-11) to a typical volume breath pattern (waveform B, Figure 4-11).



Pressure Augmentation Level	High	High	Low	Low
Ambient Demand	High	Moderate	Moderate	Low
Guaranteed V_T Relative to Demand	Lower	Higher	Higher	Higher

Figure 4-11 • Various Waveforms Achievable With Pressure Augmentation

The tidal-volume-guarantee feature of pressure augmentation ensures that the patient receives the minimum volume (even when patient demand declines) by finishing off the breath at the clinician-selected PEAK FLOW and WAVEFORM setting. The inspiratory pressure may rise above the INSPIRATORY PRESSURE control setting as is required to yield the desired tidal volume given the patient's compliance, resistance and demand. An increase in patient demand for volume is rewarded by extra flow. Thus pressure augmentation will guarantee a minimum tidal volume, but does not *limit* the patient to this minimum setting.

PRESSURE AUGMENTATION With Assist CMV & SIMV

Figure 4-12 depicts SIMV with pressure augmentation. The spontaneous breaths are all pressure-supported to the clinician set level of PRESSURE SUPPORT. Unlike the intermittent mechanical breaths, these pressure-supported breaths do not have a volume guarantee. If a volume guarantee is desired on every single breath, use ASSIST CMV with PRESSURE AUGMENT.

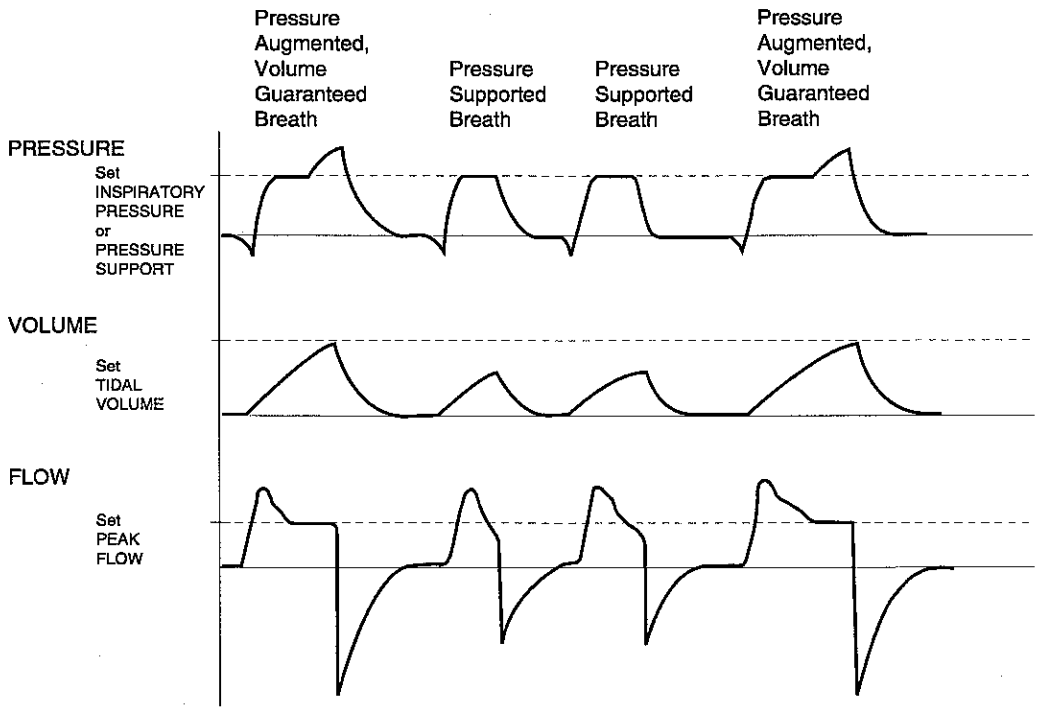


Figure 4-12 • SIMV with Pressure Augmentation

DEMAND SYSTEM

Included in all of the clinician selectable modes described, the BEAR® 1000 Ventilator offers a demand system. The system performs three important tasks.

1) It provides patient-triggered spontaneous breaths,

2) It provides additional flow and/or volume in response to high or asynchronous patient demand during volume-controlled breaths,

3) It compensates for circuit leaks.

When the patient demands a flow greater than the clinician-selected PEAK FLOW during a volume-controlled breath. The BEAR® 1000 Ventilator increases the delivered flow to ensure that proximal pressure never drops below baseline. Thus, the ventilator responds to patient demand even during a volume-controlled inspiration.

The demand system also compensates for leaks in the patient circuit or around the endotracheal cuff by adding flow, as necessary, during the exhalation phase of a breath. This "leak make-up" system accomplishes three important tasks:

1) It maintains clinician-set PEEP levels in spite of circuit leaks.

2) It allows the clinician to maintain the same sensitivity level for the ASSIST SENSITIVITY control, because it obviates the need to "dial out" autocycling which would otherwise occur with circuit leaks.

3) It dramatically reduces the likelihood of autocycling normally associated with circuit leaks.

The leak make-up system limits flow as a function of the set PEEP level. The leak, make-up system is only limited to the following flow values in the exhalation phase of the breath.

PEEP (cmH_2O)	Nominal Flow (LPM)
0	0
2	3
5	4
10	6
20	10
30	13
40	17
50	21

NOTE

If the PEEP setting is adjusted between breaths, the new flow limit may not take effect until a breath is delivered.

Refer to the *Theory of Operation* (Section 8), under the heading "Flow Delivery Logic" for more information.

BASE FLOW/FLOW TRIGGER Setup

The BASE FLOW/FLOW TRIGGER controls are setup in the same fashion as any other control. Follow the general setup guidelines provided at the beginning of this section.

NOTE

FLOW TRIGGER cannot be enabled unless BASE FLOW is set to a value greater than 0 LPM.

BASE FLOW/FLOW TRIGGER Fundamentals

The FLOW TRIGGER function provides a method of detecting a patient effort for the purpose of initiating a breath. When active, a set base flow travels down the patient circuit from the ventilator to the exhalation valve past the patient wye. BASE FLOW begins at 100 msec from the start of exhalation. If a patient draws any portion of this flow, the reduction in flow is observed by the flow sensor. When this reduction exceeds an operator-selected FLOW TRIGGER level, a breath is initiated. The pressure trigger (ASSIST SENSITIVITY) can be set independently of the flow trigger level since the first detected trigger will initiate the breath. The BASE FLOW setting has a range from 0, 2 to 20 LPM in increments of 1 LPM. A value of 0 LPM deactivates the Flow Trigger function. The FLOW TRIGGER level has a range of 1 LPM to 10 LPM in increments of 0.5 LPM. FLOW TRIGGER is available in all ventilator modes.

DEMAND FLOW is available to the patient even when FLOW TRIGGER is enabled. If a FLOW TRIGGER setting exceeds the BASE FLOW value, the patient will be required to draw the difference from the DEMAND FLOW SYSTEM.

A breath to breath "learn" mechanism was implemented to allow the ventilator to overcome discrepancies in delivered and exhaled flows due to humidity, device tolerance and leaks. A reduction in flow (delivered by the FLOW CONTROL VALVE) measured by the FLOW SENSOR of up to 1/2 of the BASE FLOW setting will be learned by the FLOW TRIGGER mechanism, resulting in improved trigger sensitivity.

BASE FLOW/FLOW TRIGGER Operation

Before enabling the BASE FLOW/FLOW TRIGGER feature, review the WARNINGS and CAUTIONS.

WARNING

Excessive water in the circuit may cause autocycling when using low levels of FLOW TRIGGER.

The use of external flows to power an in-line nebulizer is not recommended, as this may inhibit the patient's ability to trigger the ventilator.

Be sure to adjust BASE FLOW to the needs of each patient. Higher than necessary BASE FLOW levels may cause inadvertent PEEP and higher mean airway pressures.

Always evaluate the FLOW TRIGGER sensitivity any time there are changes made to the BASE FLOW setting to verify appropriate response at the new setting, thus minimizing needless trigger work incurred by patient.

1. Depress the BASE FLOW softkey on the control panel, then use the SET knob to select the appropriate BASE FLOW level.
2. Depress the FLOW TRIGGER softkey on the control panel, then use the SET knob to select the appropriate FLOW TRIGGER level.

If a Flow Sensor Disconnect is detected while Flow Triggering is enabled, a Low Total Minute Volume alarm will be activated and "FLO" will appear in the display window. During this alarm condition, the BASE FLOW setting will remain active and Pressure Triggering will be the backup method for triggering the ventilator.

NOTE

To prevent unwanted breathing off of the demand system, always establish a FLOW TRIGGER level at least 2 LPM below the BASE FLOW level.

NOTE

If the ASSIST SENSITIVITY is set at a pressure level equal to the negative pressure generated by a FLOW TRIGGER breath, the clinician may not be able to evaluate whether the breath was a pressure-triggered or a flow-triggered breath.

CAUTION

The Flow Sensor is used to establish a FLOW TRIGGER baseline. If the FLOW SENSOR becomes disconnected while FLOW TRIGGERING is enabled, perform the following procedure.

1. ***Reattach the Flow Sensor and press the Manual Breath button to reestablish a baseline and start FLOW TRIGGER.***
2. ***Verify the patient is again triggering the ventilator, and all alarms have self-corrected.***
3. ***Press Alarm Reset***

The Flow Sensor is an integral part of the FLOW TRIGGER system. If a RUN DIAGNOSTICS alarm is activated with an E-34 or E-35 error code (Flow Sensor Fault), Flow Triggering should be discontinued. If an E-34 or E-35 condition is active, possible de-sensitivity to patient effort will occur.

5. PANEL DETAILS & SPECIFICATIONS

OVERVIEW

The following pages provide an orientation to the front panels on the BEAR® 1000 Ventilator. Included is a description of:

- how the keys function,
- how the LEDs simplify the ventilator operation, and
- how the panels are arranged into logical groupings (Monitors, Alarms and Controls).

Beyond this general orientation, details are provided for:

- every key and LED indicator, as well as
- all the physical, environmental, pneumatic and electrical specifications.

Controls	Specifications	Basic Model	Intermediate Model	Comprehensive Model
Mode	Assist/CMV, SIMV/CPAP (PSV)	X	X	X
	Pressure Control		X	X
	PC-SIMV			X
Tidal Volume	0.10 to 2.00 L	X	X	X
	0.03 to 2.00 L		X	X
Rate	0, 0.5, 1 to 120 BPM	X	X	X
Peak Flow	10 to 150 LPM	X	X	X
	5 to 150 LPM		X	X
%O_2	21 to 100%	X	X	X
Pressure Support	0 to 80 cmH_2O	X	X	X
Assist Sensitivity	0.2 to 5 cmH_2O	X	X	X
PEEP/CPAP	0 to 50 cmH_2O	X	X	X
Inspiratory Pause	0 to 2 Seconds	X	X	X
MMV Level	0 to 50 LPM		X	X
Compliance Comp.	0 to 7.5 ml/cmH_2O		X	X
Inspiratory Time	0.1 to 5 Seconds		X	X
Pressure Slope	-9 to +9 and P-9 to P+9		X	X
Waveforms	Square, Decelerating, Sine	X	X	X
Manual Breath	xl	X	X	X
Manual Inspiratory Pause	2 Seconds Maximum	X	X	X
Expiratory Hold	9 Seconds Maximum		X	X
100% O_2	On/Off-3 Minutes Auto Off	X	X	X
Sighs	On/Off-Every 100 Breaths at 150% of set V_T	X	X	X
	Every 100 Breaths at 150% of set Tidal Volume			
Pressure Augmentation	On/Off		X	X
Nebulizer	On/Off-30 Minutes Auto Off	X	X	X
Panel Lock	On/Off	X	X	X
Set Knob	No End Stop	X	X	X
Inspiratory Pressure	0 to 80 cmH_2O		X	X
Base Flow	0, 2 to 20 LPM			X
Flow Trigger	1 to 10 LPM			X
Monitors				
Breath Type Indicators				
Controlled Breath	LED On/Off	X	X	X
Sigh Breath	LED On/Off	X	X	X
Patient Effort	LED On/Off	X	X	X
MMV Active	LED On/Off		X	X
Tidal Volume	0.00 to 9.99 L	X	X	X
Total Minute Volume	0.0 to 99.9 LPM	X	X	X
Spontaneous Minute Volume	0.0 to 99.9 LPM	X	X	X
Total Rate	0 to 155 BPM	X	X	X
Spontaneous Rate	0 to 155 BPM	X	X	X
I:E Ratio	1:0.1-1:99.9	X	X	X
Inspiratory Time (T_I)	0.0 to 9.99 Seconds			X
MMV%	0 to 100%		X	X
Peak Pressure	0 to 140 cmH_2O	X	X	X
Mean Pressure	0 to 140 cmH_2O	X	X	X
Plateau Pressure	0 to 140 cmH_2O	X	X	X

Alarms	Specifications	Basic Model	Intermediate Model	Comprehensive Model
Indicators				
Time/I:E Limit	LED On/Off	X	X	X
Run Diagnostics	LED On/Off	X	X	X
Gas Supply	LED On/Off	X	X	X
Failed to Cycle	LED On/Off	X	X	X
I:E Override	LED On/Off		X	X
Total Minute Volume				
High	0 to 80 LPM	X	X	X
Low	0 to 50 LPM	X	X	X
Total Breath Rate				
High	0 to 155 BPM	X	X	X
Low	1 to 99 BPM	X	X	X
Peak Inspiratory Pressure				
High	0 to 120 cmH_2O	X	X	X
Low	3 to 99 cmH_2O	X	X	X
Baseline Pressure				
High	0 to 55 cmH_2O		X	X
Low	0 to 50 cmH_2O		X	X
Alarm Silence	60 Seconds	X	X	X
Visual Reset	Activate	X	X	X
Panel Dimmer	High/Low	X	X	X
Panel Lock	On/Off	X	X	X
Test	Activate	X	X	X
Alarm Set Knob	No End Stop	X	X	X

Preset Values

Minimum Expiratory Time ..... 250 milliseconds
Maximum Inspiratory Time ..... 5 Seconds
Maximum Working Pressure .... 120 cmH_2O
Maximum System Pressure ..... 175 cmH_2O

Outputs

Digital ..... RS-232 Bi-Directional, Baud Rates
..... of 1200, 2400, 9600, or 19200
Proximal Pressure ..... -60 to +140 cmH_2O, 1 cmH_2O/25 mV
Flow ..... -300 to 200 LPM, 1 LPM/10 mV
Remote Alarm ..... Logic High/Low Signal

Inputs

Electrical ..... 95-135V, 60 Hz (U.S./International)
..... 80-110V, 50/60 Hz (International)
..... 176-242V, 50/60 Hz (International)
..... 192-264V, 50/60 Hz (International)

Pneumatic

Oxygen and Air ..... 30 to 80 psig

Physical Dimensions and Shipping Information

Weight
Ventilator ..... 54 lbs.
Graphics Display ..... 5.5 lbs.
Cart ..... 55 lbs.
Compressor ..... 114 lbs.

Dimensions
Ventilator ..... 23"W x 13.5"D x 15"H
Graphics Display ..... 13.5"W x 2.5"D x 9.5"H
Cart ..... 19"W x 23"D x 31.5"H
Compressor ..... 22.5"W x 23.6"D x 33"H

Shipping Weight
Ventilator ..... 82 lbs.
Graphics Display ..... 13 lbs.
Cart ..... 65 lbs.
Compressor ..... 130 lbs.

Shipping Dimensions
Ventilator ..... 28"W x 27"D x 19"H
Graphics Display ..... 16"W x 13"D x 11"H
Cart ..... 20"W x 24"D x 35"H
Compressor ..... 23.8"W x 27.5"D x 39.5"H

Tolerances

Tidal Volume:
67 ml to 2.0 L
Greater of, ± 0.02 L or ± 10% of setting
30 to 66 ml
Greater of, ± 10 ml or ± 30% of setting
Rate:
0 to 60 BPM
± 1 BPM
61 to 100 BPM
± 2%
101 to 120 BPM
± 3%
Exhaled Volume:
Set Tidal Volume ≥ 0.1 L
Greater of, ± .03 L or 10% of delivered volume
Set Tidal Volume 30 to 99 ml
± 20 ml of delivered volume
Monitored Rate:
Greater of, ± 3% or 2 BPM
Peak, Mean and Plateau pressure monitors
Greater of, ± 3.5% or ± 2 cmH_2O

Emissions/Susceptibility

MIL-STD-461D:1993, MIL-STD-462D:1993, EN55011:1991, German Postal Law Vfg 243:1991, IEC 601-1-2 (CISPR11; Class B),IEC 801-2:1991, IEC 801-3:1993, IEC 801-4:1988, IEC 801-5:1993, Quasi-Static:1993
This ventilator is designed and manufactured to comply with the safety requirements of IEC 601-1, IEC 601-2-12, CAN/CSA-C22.2 No. 601.1-M90, and UL 2601-1.

Classification

The BEAR® 1000 Ventilator is a Class 1, type B device.

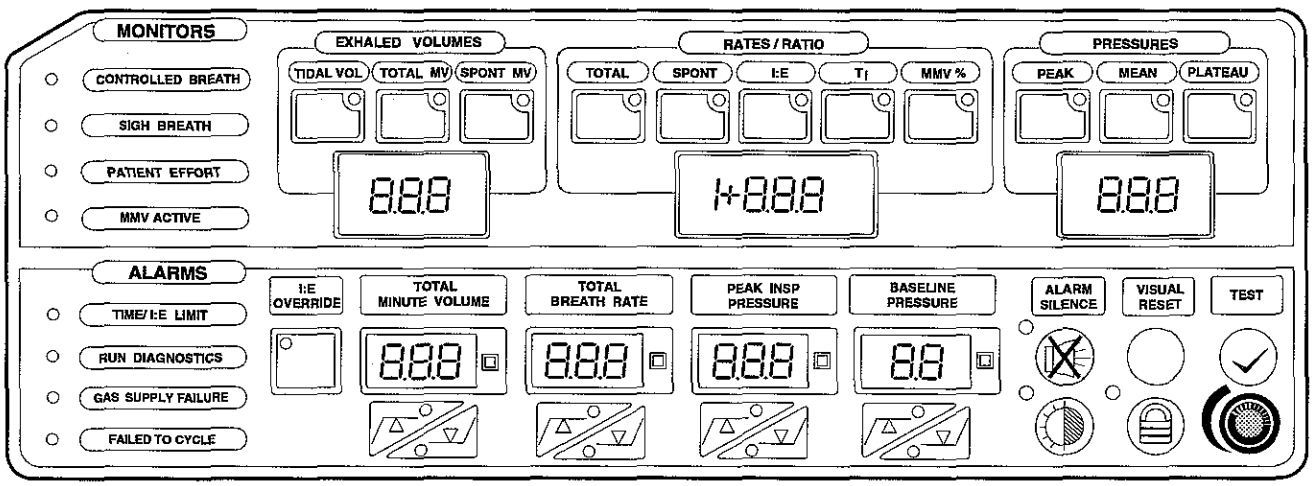
LAYOUT

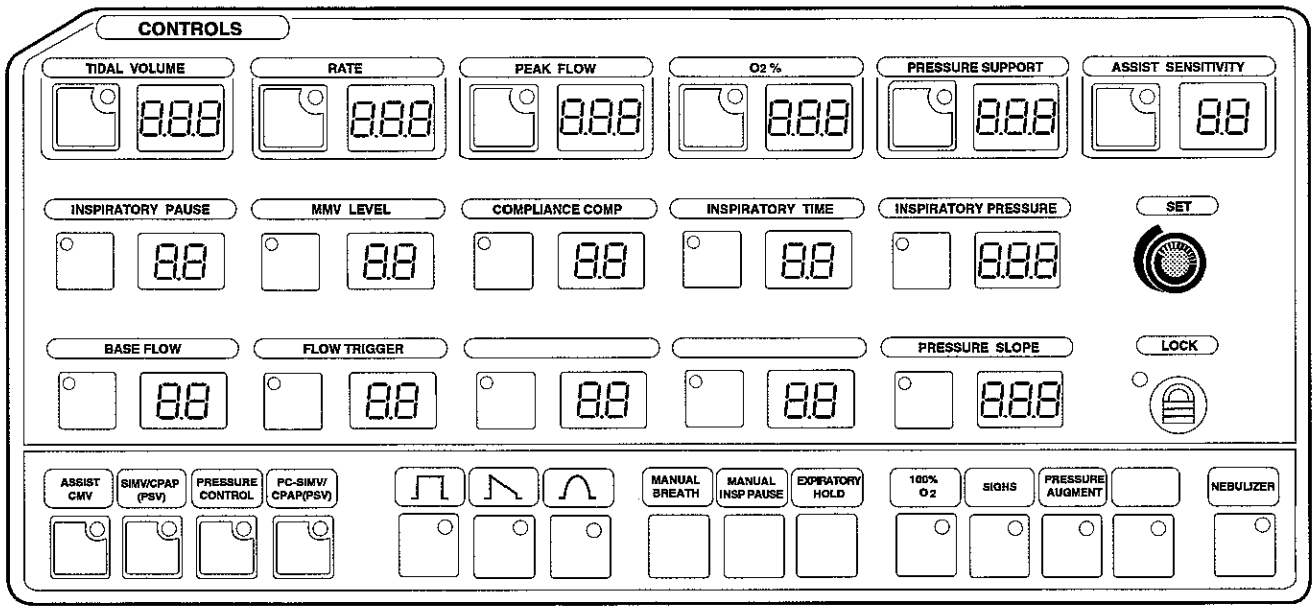
The BEAR® 1000 Ventilator front panel is divided into three primary groups:

- Monitors (outlined in yellow)
- Alarms (outlined in red)
- Controls (outlined in green)

The last of these, "Controls," is divided into two subsets. The Upper Control Group includes all of the controls which have a setting level, such as TIDAL VOLUME, RATE, INSPIRATORY PAUSE and BASE FLOW. The Lower Control Group includes all of the controls which toggle "on" or "off" (no exact level can be set). Included here are MODE keys, WAVEFORM keys, the MANUAL BREATH key.

A fourth area of the front panel contains the analog manometer and the PEEP control knob, positioned just below it.





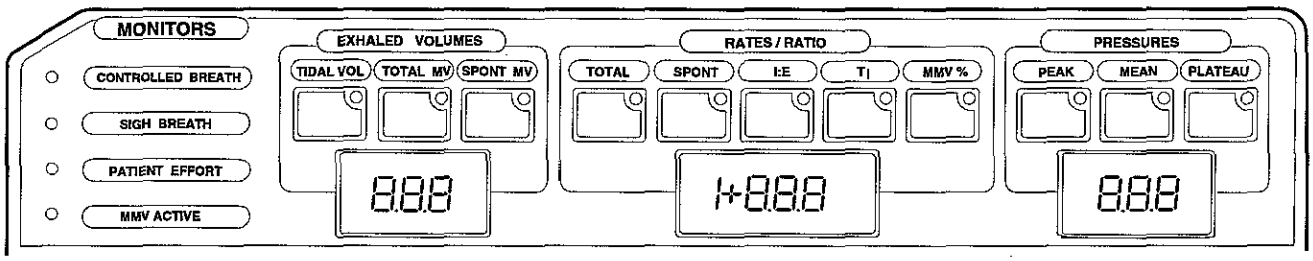
FUNCTION

The panels on the BEAR® 1000 Ventilator use LED displays combined with knobs.

The LED displays on the BEAR® 1000 Ventilator do more than just display user settings. They also convey information—such as which controls are available in each operating mode.

Once the power is on, certain settings appear in the displays. These settings are stored in memory indefinitely and reflect the last clinician settings.

Notice also that whenever a key is pressed on the front panel, a low sounding tone verifies the action.



MONITORS

The patient monitors are located in the top of the front panel in the yellow "Monitor Group." All key options available on the BEAR® 1000 Ventilator are described in following pages. Readers can determine relevant information based upon the particular ventilator configuration they own.

Note that the left side of the Monitor Group includes Breath-type Indicators. These indicators light whenever a breath is detected. For example, if the machine delivers a volume-controlled breath in the SIMV mode, the CONTROLLED BREATH LED will light. In addition, if the patient exerts some effort to trigger this volume breath, the PATIENT EFFORT indicator will also light. Together these Breath-type indicators enable the clinician to identify the type of breath currently being delivered. All monitors update at the start of the next inspiration or every 10 seconds, whichever comes first.

The remainder of the Monitor Group is divided into three basic functions:

- Exhaled Volume Monitoring which conveys either Tidal Volume, Total Minute Volume, or Spontaneous Minute Volume.
- Rates & Ratio Monitoring which conveys Total Breath Rate, Spontaneous Breath Rate, I:E Ratio, T_i or MMV %.
- Pressure Monitoring compliments the continuous pressure monitoring of the analog manometer by conveying Peak Pressure, Mean Pressure, or Plateau Pressure.

To reduce display complexity and permit the use of larger easily read LEDs, only the user selected exhaled volume is displayed.

If tidal volume is currently displayed in the numerical LED area for "Exhaled Volumes," the indicator on the TIDAL VOL key is lit. To change the display to monitor spontaneous exhaled minute volumes, press the SPONT MV key, and the key indicator lights while the TIDAL VOL indicator turns off.

CONTROLLED BREATH

Controlled Breath

Panel Group: Monitors
Range: on, off
Modes Used in: All
This breath-type indicator lights whenever a volume-controlled, pressure augmented or a pressure-controlled breath is delivered. It does not light for a spontaneous breath or a pressure-supported breath. Beside the usual controlled breaths, it lights for a sigh breath and a manual breath. This indicator will stay on throughout the inspiration phase of the breath.

SIGH BREATH

Sigh Breath

Panel Group: Monitors
Range: on, off
Modes Used in: All except Pressure Control and PC-SIMV
This breath-type indicator lights whenever a sigh breath is delivered. This indicator updates on a breath-by-breath basis, and it stays on only during the inspiration phase of a sigh breath.

PATIENT EFFORT

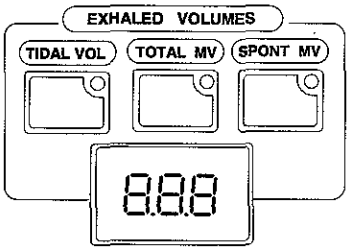
Patient Effort

Panel Group: Monitors
Range: on, off
Modes Used in: All
This breath-type indicator lights whenever the patient exerts an effort which is equal to or greater than the clinician-selected ASSIST SENSITIVITY or FLOW TRIGGER level. (The indicator functions during volume-controlled, spontaneous, pressure-supported, pressure-controlled and PC-SIMV breaths.) As long as a patient effort is detected, a PATIENT EFFORT indicator stays on.

MMV ACTIVE

MMV Active

Panel Group: Monitors
Range: on, off
Modes Used in: SIMV and CPAP
This breath-type indicator lights continuously whenever the MMV backup rate is active.



Exhaled Volume

Panel Group: Monitors
Default: Tidal Volume
Modes Used in: All
Exhaled volumes are measured by the flow sensor located on the front left side of the ventilator. Tidal Volume readings reflect only the most recent breath. The Minute Volume display (TOTAL MV and SPONT MV) is not an average, but represents the actual exhaled volumes accumulated over a one minute period. Due to the method of calculation, the value shown at update time may be delayed by up to 0.5 seconds.

Both the exhaled volume measurements and the delivered set TIDAL VOLUME use the STPD standard (Standard Temperature 77°F (25°C), set ambient barometric Pressure, Dry gas). However, patient exhaled gases are normally saturated with moisture to 100% Relative Humidity. To express the exhaled gas volume on a consistent STPD basis with the delivered TIDAL VOLUME, the BEAR® 1000 Ventilator accurately subtracts out volume attributed to humidity. As a result of this patient-oriented correction, exhaled volumes from test lungs, which do not add humidity, read 0 to 4% low.

NOTE

When the flow sensor is first connected to the ventilator or at power-up, the Tidal Volume Monitor will not be active for a period of 10 seconds. This is to allow the ventilator to read data from the flow sensor and purge the pressure sense lines.

TIDAL VOL

Range: 0.00 to 9.99 Liters (0 to 999 ml- Lower Tidal Volume feature)
Increment: 0.01 Liters (1 ml - Lower Tidal Volume feature)
TIDAL VOL displays the exhaled tidal volume of the last breath, regardless of breath type.

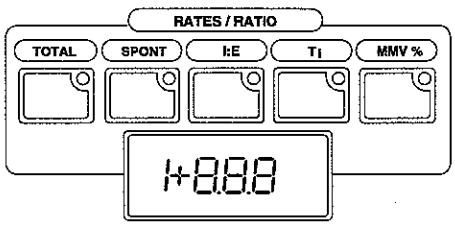
NOTE

Tidal Volume Monitor will display in ml's only when the following conditions are satisfied.

- Mode is A/C or SIMV
- Tidal Volume control is set between P30-P99

TOTAL MV
Range: 0.0 to 99.9 LPM
Increment: 0.1 LPM
TOTAL MV displays measured exhaled minute volume for all breaths, both demand and machine-controlled.

SPONT MV
Range: 0.0 to 99.9 LPM
Increment: 0.1 LPM
SPONT MV displays measured exhaled minute volumes for all demand breaths, including both spontaneous and pressure-supported.



Rates/Ratio

Panel Group: Monitors
Default: Total
Modes Used in: All
The RATE display (TOTAL and SPONT) is not an average, but represents the actual number of breaths accumulated over a one minute period. Due to the method of calculation, the value shown at update time may be delayed by up to 0.5 seconds. These values fully respond to any step change within one (1) minute.

TOTAL
Range: 0 to 155 BPM
Increment: 1 BPM
TOTAL displays the number of breaths inspired per minute, including both demand and machine-controlled breaths.

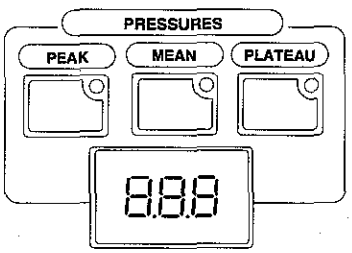
SPONT
Range: 0 to 155 BPM
Increment: 1 BPM
SPONT displays the number of demand breaths inspired per minute. Both spontaneous and pressure-supported breaths are included as "demand breaths."

I:E RATIO
Range: 1:0.1 to 1:99.9
Increment: 0.1
I:E RATIO is expressed in this display as follows: {1 : (Te/Ti)} where: Ti is inspiratory time and Te is expiratory time. The I:E Ratio reading is not an average, but rather reflects the exact ratio for the last completed machine breath. (It is updated upon the initiation of inspiration of the next breath.) The I:E Ratio

Monitor reflects only volume-controlled and pressure-controlled breaths, but not spontaneous or pressure-supported breaths.

T_i
Range: 0 to 9.99 seconds
Increments: 0.01 seconds
T_i displays the Inspiratory Time of the previous breath for all Volume, Pressure Controlled and Demand Breaths. If Inspiratory pause is enabled, this will be included in the measurement of this value.

MMV %
Range: 0 to 100%
Increment: 1
MMV% displays the percentage of time during the last half hour that the MMV backup rate has been used rather than the normal breath RATE control. The MMV % reading represents a 30-minute average. When the ventilator is powered up, the MMV% monitor is re-zeroed.

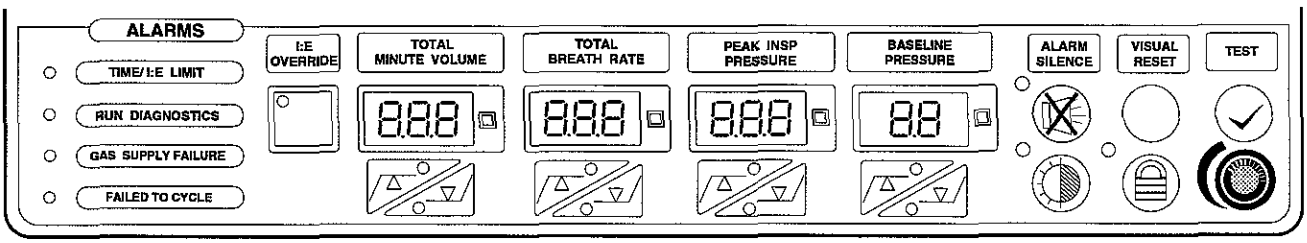


Pressures
Panel Group: Monitors
Default: Peak
Modes Used in: All
Proximal pressure readings are displayed in the Monitor Group, as well as on the analog manometer. The MEAN pressure fully responds to any step change within 30 seconds.

PEAK
Range: 0 to 140 cmH2O
Increment: 1
PEAK pressure displays the peak pressure reading during the inspiratory phase of the last positive pressure breath (eg, volume-controlled, pressure-supported, or pressure controlled, but not spontaneous breaths).

MEAN
Range: 0 to 140 cmH2O
Increment: 1
MEAN pressure displays the average pressure at the patient wye over the last 30 second period.

PLATEAU
Range: 0 to 140 cmH2O
Increment: 1
PLATEAU pressure displays the inspiratory plateau pressure during the previous breath. A plateau of 0.1 seconds is sufficient to create a monitored PLATEAU pressure reading. However, if no plateau existed on the previous breath, the PLATEAU monitor reads zero.



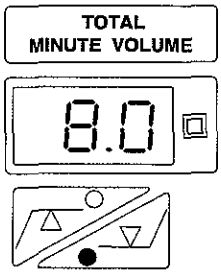
ALARMS

Alarms are in red on the front panel of the BEAR® 1000 Ventilator. On the left side of the Alarm Group are indicators for built-in alarms. For example, when the preset "Inspiratory to Expiratory" time ratio has been reached, the TIME/I:E LIMIT indicator flashes. The LED continues flashing until the alarm-causing condition is corrected. At this point, the LED quits flashing, but it is "latched" (remains lit to notify the clinician that the alarm was violated). To release the "latching", press the VISUAL RESET key. In a similar fashion, when other built-in alarms are violated, their indicators flash.

Next to the built-in alarm indicators is the I:E OVERRIDE key. When this override is not activated, the key LED indicator is off and the maximum allowed "Inspiratory time to Expiratory time" Ratio is set at 1:1. The clinician can override this limit and allow inverse ratio ventilation by pressing the I:E OVERRIDE key once. The key indicator lights, and the new inverse ratio I:E limit is used.

The Alarm Group has four user-adjustable alarms, and each has a high and a low limit:

- TOTAL MINUTE VOLUME
- TOTAL BREATH RATE
- PEAK INSP PRESSURE
- BASELINE PRESSURE.



All of these alarms are adjusted in the same fashion; therefore, only one is described in detail here.

The TOTAL MINUTE VOLUME alarm has a single red numerical LED display for both high and low alarms. Notice the two keys below the LED. The key on the upper left is for the high alarm setting, and that on the lower right is for the low alarm level. If the LED in the low alarm limit key is lit, the value in the numerical LED is the low alarm limit.

To view or adjust the upper alarm limit, press the upper alarm key, and its numerical value appears in the LED. Likewise its key indicator begins to flash, and the lower alarm key LED turns off.

Whenever a key indicator flashes, the setting level for that key can be adjusted with the associated SET knob. Once the alarm key is pressed, the indicator flashes for 15 seconds. During this time, the user may adjust the alarm level by turning the red SET knob. Whenever the user moves the SET knob, the 15-second period resets, thereby extending the adjustment time.

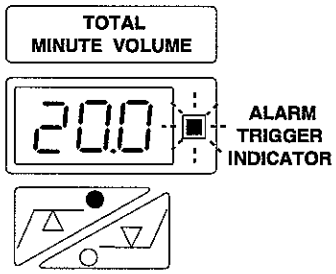
Any other alarm can be adjusted before the 15-second period elapses by pressing the new alarm key, observing its key indicator flash, and turning the SET knob (only one alarm key indicator can flash at any given time).

Note that changes in alarm levels take effect the instant that the knob is turned, even while the key LED continues to flash.

Naturally, the SET knob only allows the user to adjust the alarms within the functional limits of the machine. When the limits are reached, a warning beep will sound.

During ventilation, if an alarm is triggered:

- the ventilator will sound an alarm,
- the Alarm Trigger Indicator will flash.



The Alarm Trigger Indicator, located right of the numerical LED display, continues to alert the user of the alarm violation until the alarm condition is no longer violated. The Trigger Indicator quits flashing and remains lit until the user presses the VISUAL RESET key.

Five other keys are located in the right portion of the Alarm Group: ALARM SILENCE, DIMMER, VISUAL RESET, PANEL LOCK and TEST. These initiate an action, or can be set either "on" or "off". When "on," the LED indicators light.

Once depressed and with the key indicator lit, the panel lock allows the user to view any setting, but not to change any alarm settings. This feature helps prevent inadvertent changes to the alarm settings.

Time/I:E Limit

Panel Group: Alarms
Range: on, off
Modes Used in: All
TIME/I:E LIMIT reports the status of these two built-in alarms. There are two circumstances which cause this indicator to light:

1) When the monitored inspiratory time exceeds the sum of 5 seconds plus the INSPIRATORY PAUSE time, or

2) When the I:E ratio (due to machine-controlled breaths only) reaches the set limit.

When either alarm is triggered:
- the indicator flashes,
- an alarm sounds, and
- inspiration terminates.

The set I:E limit is normally 1:1. Expiratory times shorter than inspiratory times are normally prohibited because the ventilator will sound an alarm and terminate inspiration. However, the clinician can override this 1:1 limit as described in the I:E OVERRIDE alarm specification.

Note that whereas the I:E RATIO monitor updates when one breath ends and the next begins, the I:E LIMIT alarm indicator updates continuously and can curtail an inspiration when the I:E LIMIT is exceeded.

○ RUN DIAGNOSTICS

Run Diagnostics

Panel Group: Alarms
Range: on, off
Modes Used in: All
RUN DIAGNOSTICS reports the results of ongoing electronic self-checks. If a major subsystem or electronic failure is detected, an attending troubleshooting code can be viewed in the TOTAL MINUTE VOLUME alarm LED by pressing the TEST key. To clear the display, press VISUAL RESET.

○ GAS SUPPLY FAILURE

Gas Supply Failure

Panel Group: Alarms
Range: on, off
Modes Used in: All
GAS SUPPLY FAILURE reports gas supply status. When the gas supply pressure drops below 27.5 psig, the GAS SUPPLY FAILURE indicator lights, and an alarm sounds. During the alarm, the ventilator continues providing ventilation using the gas source still being supplied at or above 28.5 psig.

WARNING

When a GAS SUPPLY FAILURE occurs, the oxygen concentration to the patient will be different than that set on the O_2% control.

Loss of the Oxygen sources gas will NOT activate a GAS SUPPLY FAILURE if the set O_2% control is at 21% (AIR). Loss of Oxygen source gas will activate a GAS SUPPLY FAILURE with all O_2% control settings greater than 21%.

If only air is being used (i.e., O_2% set at 21%), only a pressure drop in the air supply causes an alarm.

Failure of both gas supplies not only causes the GAS SUPPLY FAILURE alarm indicator to light, but also the FAILED TO CYCLE indicator.

○ FAILED TO CYCLE

Failed to Cycle

Panel Group: Alarms
Range: on, off
Modes Used in: All
If the ventilator fails to cycle due to an internal or external condition, this indicator lights, an alarm sounds, and an error code appears in the TOTAL MINUTE VOLUME alarm LED.

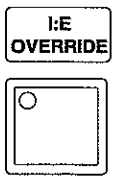
"Failure to cycle" means the ventilator is not providing any mechanical breaths or demand flow. During FAILED TO CYCLE or a power failure, the SOPR valve opens and the patient breathes room air. The audible alarm cannot be silenced during a FAILED TO CYCLE until the ventilator is shut off and removed from the patient.

When a gas supply failure is the cause of the FAILED TO CYCLE, no error code appears in the MINUTE VOLUME alarm LED.

When a power failure is the cause of the FAILED TO CYCLE, an alarm will sound for a minimum of 5 minutes (or until power is restored). The ventilator has sufficient backup power to support this alarm; however, there is no visual alarm indicator.

WARNING

During a FAILED TO CYCLE condition, no PEEP will be maintained.



I:E Override

Panel Group: Alarms
Range: on, off
Default: off
Modes Used in: All

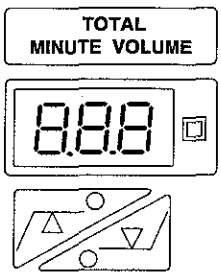
The ventilator has a built-in I:E time limit of 1:1. Inspiratory time cannot exceed 60 ÷ (2 x Breath Rate) unless the clinician overrides the built-in limit by pressing the I:E OVERRIDE alarm key.

When the built-in 1:1 limit is overridden, the I:E OVERRIDE LED indicator lights, and the new 1:0.25 I:E limit takes effect (equivalent to allowing 4:1 ratio ventilation).

WARNING

Auto-PEEP is not always accurately measured by a proximal pressure reading during mechanical ventilation. This is particularly true during PC-IRV where lung pressure and circuit pressure may not reach equilibrium prior to the initiation of a new breath. The short expiratory times associated with Inverse Ratio Ventilation may result in incomplete exhalation and, as a consequence, lead to gas trapping (Auto-PEEP) and patient compromise.

Accordingly, any patient being ventilated should be monitored closely. This can be done either manually or by use of the expiratory hold button.

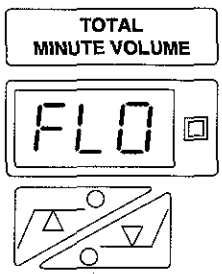


Total Minute Volume

Panel Group: Alarms
Modes Used in: All
This alarm continuously compares the monitored value for minute volume with its high and low alarm settings. When either of these settings is violated, an alarm sounds, and the alarm trigger indicator flashes (at the right of its numerical display). If the low alarm setting is violated, the low alarm setting level automatically displays. Similarly, a violation of the high alarm limit causes that setting to display.

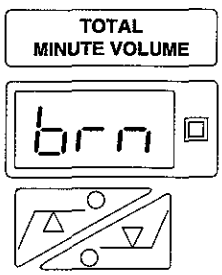
Another important function of the TOTAL MINUTE VOLUME LED is to display troubleshooting codes. Press the TEST key to view the last recorded troubleshooting code in the TOTAL MINUTE VOLUME LED. Then press VISUAL RESET to clear this code.

Low TOTAL MINUTE VOLUME
Range: 0 to 50 Liters
Increment: 0.1 Liters
Default: 0



If a flow sensor disconnect is detected while flow triggering is enabled, a LOW TOTAL MINUTE VOLUME alarm will be activated and "FLO" will appear in the display window. During this alarm condition, the base flow setting will remain active and pressure triggering will be the backup method for triggering the ventilator.

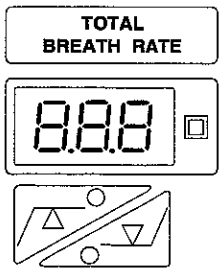
High TOTAL MINUTE VOLUME
Range: 0 to 80 Liters
Increment: 0.1 Liters
Default: 50



When the external power supplied to the ventilator falls below the specified operating voltage, the device will alarm Fail to Cycle with an E-39 (Low Line) error code. If power subsequently rise above the low line value within a short period of time, and remains so for a period greater than 5 seconds, the ventilator will recover and begin ventilation. This is considered a external power "Brown-out" condition. To assist the user in identifying a possible transient power line condition, the ventilator will alarm while displaying a "brn" in the Total Minute Volume alarm window. An E-42 error will also be stored in the error history queue.

NOTE

If the ventilator's power is cycled ON and OFF quickly, this will be seen by the ventilator as a Brown-out condition. When cycling the ventilator's power, allow at least 5 seconds before turning the ventilator back on.



Total Breath Rate

Panel Group: Alarms
Modes Used in: All
TOTAL BREATH RATE continuously compares the monitored value for total breath rate with its high and low alarm settings. When either of these settings is violated, an alarm sounds, and the alarm trigger indicator flashes (at the right of its numerical display). If the low alarm setting is violated, the low alarm setting level automatically displays. Similarly, a violation of the high alarm limit causes that setting to display

High TOTAL BREATH RATE
Range: 0 to 155 BPM
Increment: 1 BPM
Default: 155

Low TOTAL BREATH RATE/APNEA
Range: 1 to 99 BPM
Increments: 1 BPM
Default: 3
The Low TOTAL BREATH RATE alarm also functions as an APNEA alarm. At an alarm setting of 3 bpm or greater, the APNEA period will be 20 seconds. At an alarm setting of 2 and 1 bpm, the APNEA period will be 30 and 60 seconds, respectively. The Apnea period is reset with any breath type, spontaneous and/or mechanical.

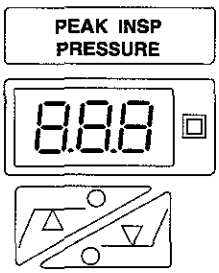
NOTE

To adjust the low TOTAL BREATH RATE alarm below 3 bpm (3 bpm is the default alarm level), the clinician must press and hold the low TOTAL BREATH RATE key while turning the SET knob to the desired setting.

If an Apneic episode is detected, both audible and visual notification of the event will be activated and "AP." will appear in the TOTAL BREATH RATE window. If an Apneic event is detected and the MMV feature is activated in either the SIMV or CPAP modes, then backup ventilation will occur (refer to MMV description in the controls section explanation).

The APNEA Period timer is reset and restarted at the start of each detected spontaneous or mechanical breath. The APNEA Alarm is activated when the time between breaths exceeds the set APNEA interval. The alarm will be de-activated upon initiation of a spontaneous or mechanical breath.

To adjust the LOW TOTAL BREATH RATE Alarm above 3 BPM, the clinician must press and hold the TOTAL BREATH RATE Key while turning the Set Knob to the desired setting.



Peak Insp Pressure

Panel Group: Alarms
Modes Used in: All
PEAK INSP PRESSURE continuously compares the monitored value for peak inspiratory pressure with its high and low alarm settings. When either of these settings is violated, an alarm sounds, and the alarm trigger indicator flashes (at the right of its numerical display). If the low alarm setting is violated, the low alarm level displays in the numerical read-out. Similarly, a violation of the high alarm limit causes that setting to display.

Low PEAK INSP PRESSURE
Range: 3 to 99 cmH_2O
Increment: 1 cmH_2O
Default: 3
This alarm cannot be set below 3 cmH_2O; accordingly, it is not active for any spontaneous breath. Neither is it active for pressure-supported or pressure-controlled breaths when the following sum is less than or equal to 3 cmH_2O:

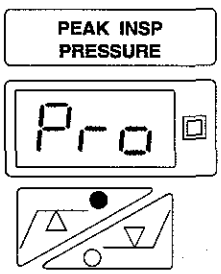
{PEEP + PRES SUP/INSP PRES}

High PEAK INSP PRESSURE
Range: 0 to 120 cmH_2O
Increment: 1 cmH_2O
Default: 120
Triggering of the High PEAK INSP PRESSURE alarm terminates inspiration. The termination of one breath does not affect delivery of subsequent breaths. Alarm violation criteria follow:

1) for all breaths except sighs, the breath terminates (and an alarm both flashes and sounds) when the monitored pressure reaches the clinician-set level for high PEAK INSP PRESSURE;

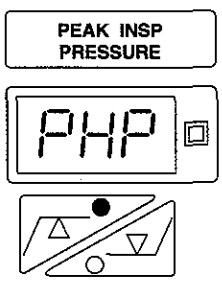
2) for sigh breaths, the breath terminates and an alarm both flashes and sounds when monitored pressure reaches either 1.5 times the high PEAK INSP PRESSURE alarm limit, or 120 cmH2O, whichever is lower.

Once a high PEAK INSP PRESSURE alarm is triggered, the BEAR® 1000 Ventilator watches to see that proximal pressure drops to within 5 cmH2O of PEEP. A kink in the expiratory leg of the circuit can prevent pressure from dropping to meet this criteria. If this happens, the BEAR® 1000 Ventilator delays delivery of the next breath until the proximal pressure does drop. High lung pressures may occur if the occlusion is not released.



Proximal Disconnect

The PROXIMAL DISCONNECT alarm activates when machine pressure measures greater than the High PEAK PRESSURE alarm setting plus 10 cmH2O. A proximal line disconnect is the most likely cause of this alarm; however, a very large leak at the ventilator or patient wye will also trigger a PROXIMAL DISCONNECT alarm. Additionally, a highly resistive inspiratory circuit due to a partially occluded bacteria filter or humidifier can also cause a "PRO" alarm. While the alarm is active "Pro" displays in the PEAK INSP PRESSURE window and the ventilator does not recognize patient triggered breaths, but both the Demand system and the Breath Rate control are active. The ventilator will deliver flow to the patient circuit in an attempt to increase the Proximal Pressure up to the PEEP setting and breaths are delivered per the clinician settings until the alarm criteria no longer exist.



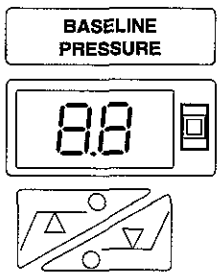
Prolonged High Pressure

The PROLONGED HIGH PRESSURE alarm activates when the High PEAK INSPIRATORY PRESSURE alarm has been activated for greater than 5 seconds. A proximal line occlusion is the most likely cause of this alarm. While the alarm is active, the SOPR valve is open to allow the non-apneic patient to breath room air and "PHP" is displayed in the PEAK INSP PRESSURE window.

The alarm will remain active for 20 seconds, then the SOPR valve is closed and the ventilator attempts to deliver another breath. Pressing of the Visual Reset during the alarm period will also reset the ventilator. This process will continue until the problem is resolved.

WARNING

During a "PHP" alarm, no mechanical breaths are delivered and PEEP will not be maintained.



Baseline Pressure

Panel Group: Alarms
Modes Used in: All
BASELINE PRESSURE continuously compares the monitored value for baseline pressure with its high and low alarm settings. When either setting is violated, an alarm sounds, and the alarm trigger indicator flashes (at the right of its numerical display). If the low alarm setting is violated, the low alarm level displays. Similarly, a violation of the high alarm limit causes that setting to display.

Low BASELINE PRESSURE
Range: 0 to 50 cmH2O
Increment: 1 cmH2O
Default: 0
Violation of this alarm will occur when BASELINE PRESSURE is less than the low BASELINE PRESSURE limit for a period greater than or equal to 0.5 seconds.

The low BASELINE PRESSURE alarm can alert the clinician to any loss in PEEP levels. Setting this alarm to zero turns off this alarm.

High BASELINE PRESSURE
Range: 0 to 55 cmH2O
Increment: 1 cmH2O
Default: 55
The High BASELINE PRESSURE alarm can alert the clinician to any air trapping conditions (also called "inadvertent PEEP," "intrinsic PEEP" or "auto-PEEP").

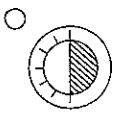
Alarm Silence

Panel Group: Alarms
Range: on, off
Modes Used in: All
Pressing ALARM SILENCE cancels the audible portion of an alarm for 60 seconds. All alarms are silenceable except the FAILED TO CYCLE alarm. A lit LED indicator adjacent to the ALARM SILENCE key reminds the clinician that alarms have been silenced until:

- 60 seconds elapse or
- the clinician presses ALARM SILENCE again.

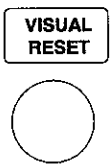
WARNING

The patient should never be left unattended when the ALARM SILENCE is activated to ensure timely detection of any new alarm conditions.



Dimmer

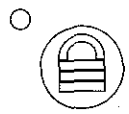
Panel Group: Alarms
Range: low, high
Modes Used in: All
The DIMMER key adjusts the brightness level of all the front panel LEDs. Two brightness levels are provided, and are accessed by a single press of this key. When the LEDs are dimmed, the DIMMER key indicator will be lit. During power up, the front panel LEDs are dimmed for lower power consumption.



Visual Reset

Panel Group: Alarms
Range: resets when pressed
Modes Used in: All
Pressing VISUAL RESET causes the ventilator to clear all solidly lit alarm trigger indicators. Note that flashing alarm indicators cannot be cleared by VISUAL RESET since the flashing signals that the underlying alarm condition is still occurring.

NOTE:
The VISUAL RESET key will also reset a "PHP" condition. See prolonged high pressure alarm condition.



Alarm Lock

Panel Group: Alarms
Range: on, off
Modes Used in: All
ALARM LOCK helps avoid inadvertent changes to Alarm Group settings. When the LED indicator next to this key is lit, no setting changes can be made to Alarm Group keys. However, both upper and lower alarm settings can be viewed by pressing the associated key. Even with ALARM LOCK enabled, three settings in the Alarm Group can still be used: VISUAL RESET, ALARM SILENCE and ALARM LOCK itself.

Test

Panel Group: Alarms
Range: on, off
Modes Used in: All plus Diagnostics
The TEST key has three functions:

1) During normal operation, it activates all audible and visual indicators for 4 seconds, allowing the clinician to verify function.

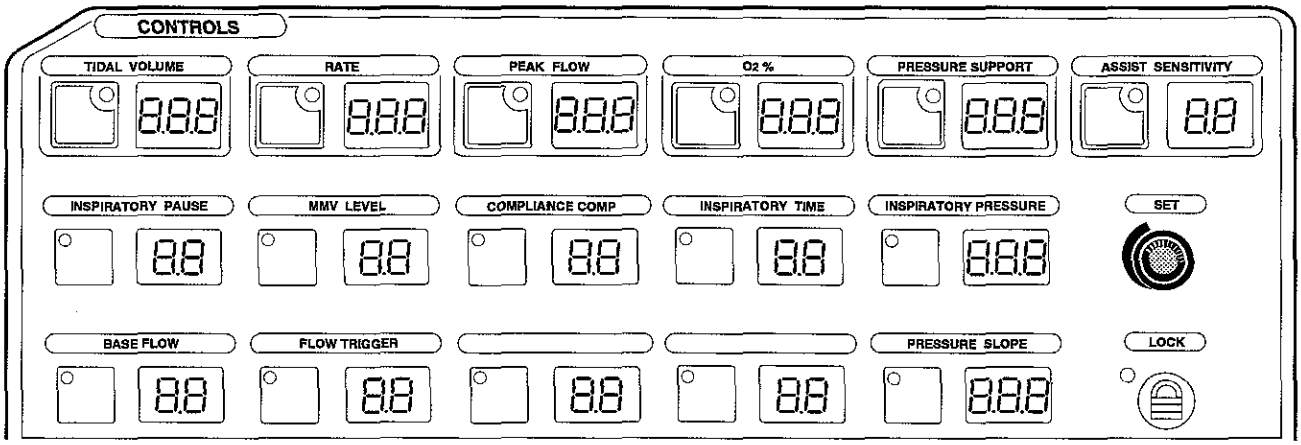
2) Also during normal operation, it causes the most recent troubleshooting code to display in the TOTAL MINUTE VOLUME alarm LED prior to being cleared. To clear this troubleshooting code, press VISUAL RESET. Once cleared, the code can only be recalled by entering the Operator Diagnostics Mode.

3) Before power-up, it causes the ventilator to enter the Operator Diagnostics by pressing and holding the key while turning on the power. The Operator Diagnostics mode is described in more detail in Sections 2 and 7 of this manual.

Set Knob

Panel Group: Alarms
Range: 360°
Modes Used in: All
The red SET knob is used in conjunction with high and low alarm limit keys to adjust settings. This knob controls the setting level of the alarm key with a flashing LED indicator. Only one such key can flash at any given time; so, only one limit is adjusted at a time by rotating the SET knob. Turn clockwise to increase a setting and counterclockwise to decrease a setting.

When the SET knob is turned to the high or low extremes of an alarm range, a low audible annunciator indicates the end of the alarm range.



UPPER CONTROLS

The top three rows of control keys located in the green control section of the BEAR® 1000 Ventilator are called the "Upper Control Group". There are five basic principles for proficient use of the Control Group keys.

1) If a key LED indicator is lit, its associated control is available in the currently selected ventilatory mode. Thus the key indicator informs the user which controls are available in each mode.

2) The numerical LED for the control setting is blank whenever:
   - it is not available for the currently operating mode.

3) A flashing key indicator means the associated control setting can be adjusted by turning the control set knob. Only one control key indicator can flash at any given time; this ensures that only one control setting will be adjusted at a time. Be aware that setting changes become operational immediately upon turning the set knob.

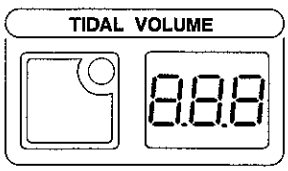
WARNING

Any adjustment to a control parameter which is available in the currently operating ventilatory mode causes an immediate change in the operating parameters.

4) There are three ways to stop a flashing key indicator:
   - wait 15 seconds
   - press a different control key, causing the new key indicator to flash
   - press the flashing key itself.

5) Any control setting can be changed at any time (provided the control panel LOCK key is not enabled) by pressing its control key, observing the flashing key indicator, and turning the set knob. This technique also applies to changing the settings for those controls which are not "available" options in a particular mode. However, once the 15-second change-setting period elapses, the numerical value for this type of control will turn off, once again indicating that this control is not available in the currently operating mode.

The Control Group has its own panel LOCK apart from that of the Alarm Group. When the LOCK is enabled, the user can view, but cannot change, any setting with three exceptions. The 100% O_2 and MANUAL BREATH keys do not lock, and neither does the LOCK itself.



Tidal Volume

Panel Group: Upper Controls
Range: 0.10 to 2.00 liters (P30 to P99 - Lower tidal Volume feature)
Increment: 0.01 Liters
Default: 0.10
Modes Used in: All except Pressure Control and PC - SIMV
This machine-delivered tidal volume key is available in all modes except the Pressure Control and PC-SIMV modes. While it is available in the CPAP mode, its setting is not used by the ventilator unless one of the following occurs:

1) a MANUAL BREATH is delivered, or
2) the MMV Backup rate is active.

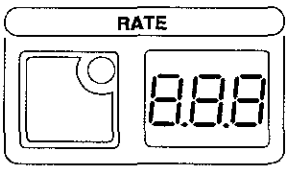
Delivered tidal volumes may exceed the set TIDAL VOLUME if the patient demands extra volume.

The tidal volume setting represents STPD (Standard Temperature 77°F, ambient Pressure, Dry). Once gas flows through a humidifier, the volume increases in response to the addition of water and the rise in temperature.

Lower Tidal Volume Feature

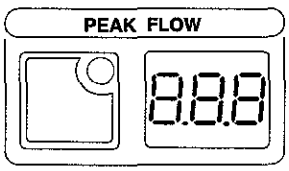
The TIDAL VOLUME control may be used to select Adult or Pediatric volumes. Selecting values in the current range is done in standard fashion. However, to switch from Adult to Pediatric ranges (and back), the clinician must press and hold the TIDAL VOLUME key while turning the SET knob to the desired setting.

The selected value will appear in milliliters proceeded by the letter "P" (e.g., P30) indicating Lower Tidal Volume.



Rate

Panel Group: Upper Controls
Range: 0.0, 0.5, 1 to 120 BPM
Increment: 1 BPM
Default: 0
Modes Used in: All
This machine breath RATE control is available in all modes. During CPAP, this control is set at zero, and as with all controls on the BEAR® 1000 Ventilator any control set to zero shows a blank numerical display.

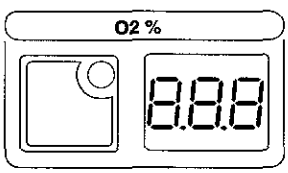


Peak Flow

Panel Group: Upper Controls
Range: 10 to 150 LPM (5 to 150 LPM - Lower Tidal Volume feature)
Increment: 1 LPM
Default: 10
Modes Used in: All except Pressure Control and PC-SIMV
PEAK FLOW operates in conjunction with the WAVEFORM keys to modulate the inspiratory flow pattern delivered to the patient during a volume-controlled breath. The maximum flow delivered to a passive patient during inspiration of a volume-controlled breath is the set PEAK FLOW level.

While PEAK FLOW is available in CPAP, it is only used by the ventilator when:

1) a MANUAL BREATH is delivered, or
2) the MMV Backup rate is active.

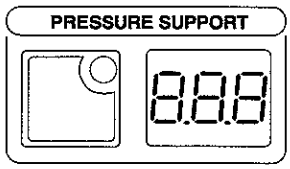


O_2%

Panel Group: Upper Controls
Range: 21 to 100%
Increment: 1 %
Default: 100
Modes Used in: All
O_2% determines the oxygen concentration delivered to the patient through the combined actions of the inlet gas blender and the accumulator.

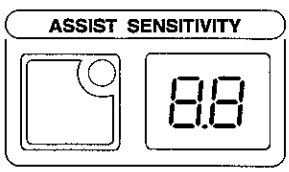
WARNING

It is suggested that oxygen concentration be monitored continuously using an oxygen monitor that includes both high and low alarms. If a high or low oxygen percent alarm is activated, an Operational Verification Procedure should be performed on both the ventilator and the external oxygen monitor. If the ventilator fails the OVP, it should be referred to an authorized service technician.



Pressure Support

Panel Group: Upper Controls
Range: 0 to 80 cmH2O
Increment: 1 cmH2O
Default: 0
Modes Used in: All (except Assist CMV)
The PRESSURE SUPPORT Control determines the inspiratory pressure level attained during a pressure-supported breath. In the SIMV/CPAP (PSV) or PC-SIMV/CPAP (PSV) mode, if pressure support is set above zero, all demand (not volume-controlled or pressure- controlled) breaths meeting the assist sensitivity or flow trigger settings are pressure supported to the level of PEEP plus the pressure setting displayed on this control. For example, with PEEP at 10 cmH2O and pressure support of 25 cmH2O, the manometer will reach 35 cmH2O during a pressure-supported breath.

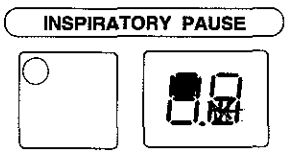


Assist Sensitivity

Panel Group: Upper Controls
Range: 0.2 to 5.0 cmH2O
Increment: 0.1 cmH2O
Default: 1.0
Modes Used in: All
ASSIST SENSITIVITY determines the amount of inspiratory effort the patient must exert to trigger either a volume-controlled breath, a pressure-controlled breath, or a pressure-supported breath. At the most sensitive point (0.2) the patient must create a sufficient effort to cause the pressure at the patient wye to drop 0.2 cmH2O below the baseline (or PEEP level) to trigger a breath.

The BEAR® 1000 Ventilator has the capability to provide leak makeup. For very small inspiratory efforts or for circuit leaks, the leak makeup system provides flow to the patient in response to a pressure drop of as little as 0.1 cmH2O.

Accordingly, a patient can receive demand flow in this manner without ever reaching the assist trigger level. However, to trigger a machine breath or to have a spontaneous effort actually counted on the RATE monitor, the assist trigger level must be reached.

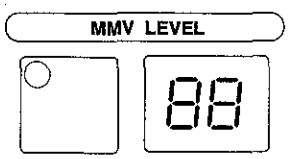


Inspiratory Pause

Panel Group: Upper Controls
Range: 0.0 to 2.0 seconds
Increment: 0.1 seconds
Default: 0.0
Modes Used in: All (except Pressure Control and PC-SIMV)
INSPIRATORY PAUSE determines the length of the pause following the delivery of the mandatory volume of a volume-controlled breath. Once the set TIDAL VOLUME is delivered, the exhalation valve remains closed for the clinician-selected INSPIRATORY PAUSE time. Flow, Volume or Pressure Augmentation can occur during this pause.

Note that long pause times in combination with certain RATE, PEAK FLOW and TIDAL VOLUME settings, may lead to an I:E LIMIT alarm.

While the INSPIRATORY PAUSE key can be used to calculate static compliance, the plateau pressure can also be obtained with the use of the MANUAL INSPIRATORY PAUSE key. The manual key automatically shuts off after a single pause is delivered.



MMV Level

Panel Group: Upper Controls
Range: 0 to 50 LPM
Increment: 1 LPM
Default: 0
Modes Used in: SIMV/CPAP
MMV LEVEL permits the clinician to select a minimum minute volume level. During ventilation in the CPAP or the SIMV modes, if the exhaled volume (as displayed by the TOTAL MV monitor) drops below the MMV LEVEL or an APNEA alarm occurs, backup ventilation is activated at a rate determined as follows:

$$\text{Backup Rate (BPM)} = \frac{\text{MMV LEVEL (Liters/min)}}{}$$

When the MMV LEVEL is violated or an APNEA alarm occurs, the calculated backup rate of ventilation is used, and breaths continue to be synchronized with patient effort. Once the monitored exhaled minute volume exceeds the MMV LEVEL by 1 liter per minute or 10% (whichever is greater) and an Assist Trigger or Manual Breath is detected, then backup ventilation is discontinued (See Figure 4-5 for additional information).

Compliance Comp

Panel Group: Upper Controls
Range: 0.0 to 7.5 ml/cmH2O
Increment: 0.1 ml/cmH2O
Default: 0.0
Modes Used in: All (except Pressure Control and PC-SIMV)
The compliance compensation factor entered via this control setting causes an additional inspiratory volume (Vadded) to be delivered during volume-controlled breaths only. This volume compensates for the volume loss due to the compliance of the gas delivery system. The volume loss varies with the type of humidification device, patient circuit and end inspiratory pressure.

The volume delivered to the circuit in any volume-controlled breath, equals the clinician-selected TIDAL VOLUME plus an additional volume determined by the compliance compensation setting as follows:

$$V_{delivered} = V_{added} + \text{TIDAL VOLUME (in milliliters)}$$

$$V_{added} = (\text{COMPLIANCE COMP}) \times (\text{End Inspiratory Pressure of Last Breath} - \text{PEEP})$$

(ml) (ml/cmH2O) (cmH2O)

Since the PEAK FLOW is the same when COMPLIANCE COMP is turned on, inspiratory time will necessarily increase to deliver the additional volume.

Note that COMPLIANCE COMP is not active during sigh breaths. The COMPLIANCE COMPENSATION VOLUME is subtracted from the displayed exhaled volume